

Standard Operational Procedures in Radiography

Document Reference No:	PTHB / RAD 004	
Version No:	5	
Issue Date:	December 2020	
Review Date:	December 2022	
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Document Owner:	Professional Head of Radiography	
Accountable Executive:	Director of Therapies & Health Science	
Approved By:	Radiation Protection Committee, Policy Group & CEO	
Approval Date:	5/12/2020, 30/03/2021 & 22/04/2021	
Document Type:	Procedure	Clinical
Scope:	Radiography and Community Dental Service staff	

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Employer Signature:

Date:

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Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Version Control

Version	Summary of Changes/Amendments	Issue Date
1	These procedures were previously incorporated within PTHB/RAD 002 Ionising Radiation Policy.	July 2015
2	Amendments made as per discussions in Radiation Protection Committee on 3 August 2016	August 2016
3	Amendments made following HIW Inspection, September 2016. Updated policy discussed and approved in Radiation Protection Committee on 24 January	January 2017
4	Amendments made following HIW Inspection, November . Update policy discussed and approved virtually via the Radiation Protection Committee Members January 2018	January 2018
5	Amendments made and agreed at Radiation Protection Committee December 2020	December 2020

Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document:

Role / Designation
Radiology Service

Circulated to the following for Consultation:

Date	Role / Designation
December 2020	Radiation Protection Committee

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1. Introduction

Please note that of the fourteen Employer's Procedures specified in schedule 2 of IR(ME)R the procedures for the assessment of patient dose and administered activity are covered in the Powys Teaching Health Board Standard Operating procedures. No radioactive substances are administered to patients within Powys.

These procedures underpin and should be read in conjunction with:

- PTHB/RAD 002 Ionising Radiation Policy

2. Objective

To support the RAD 002 Ionising Radiation Safety Policy.

3. Definitions

PTHB – Powys Teaching Health Board

4. Roles / Responsibilities

Specific role/responsibilities are described within RAD 002 Ionising Radiation Policy.

5. Monitoring Compliance / Audit

Compliance monitoring information and audit schedules are detailed within the individual Standard Operating Procedures.

6. Review and Change Control

This document will be reviewed every year or earlier should audit results or changes to legislation / practice within PTHB indicate otherwise.

STANDARD OPERATING PROCEDURE A

Ionising Radiation (Medical Exposure) Regulations Schedule 1(a) To identify correctly the individual to be exposed to ionising radiation (Procedure for Patient Identification)

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1. Introduction

Schedule 2 (i) (a) of the Ionising Radiation (Medical Exposure) Regulations [SI 1322] states that the Employer shall have in place a written procedure to correctly identify the individual exposed to ionising radiation.

The purpose of this procedure is to ensure the correct patient is examined and that the correct examination is undertaken corresponding to the clinical details provided at the intended time. Every medical exposure of ionising radiation must be justified. This protocol aims to ensure that no patient should receive an unnecessary dose of radiation due to an identification problem, or undergo any unnecessary MRI or Ultrasound procedure.

This procedure must be followed for every patient who is undergoing any form of examination which involves ionising radiation. This procedure must also be followed by those professionals within Radiology responsible for undertaking non-ionising radiation examinations e.g. Ultrasound.

2. Scope

This procedure is intended solely for the use of members of staff within PTHB. This procedure is cross-departmental, and applies to all staff involved with the identification of patients referred for any radiological examination using ionising radiation (X-rays) or non-ionising radiation including Ultrasound.

It is the responsibility of the Operator making the X-ray exposure, or performing the Ultrasound scan to ensure that this procedure is carried out.

Examinations must not commence unless the IR(ME)R operator (Radiographer, Radiologist, Dentist or entitled mini c-arm operator) initiating the exposure of ionising radiation is satisfied that the patient's identity is correct.

In the situation where there are multiple Operators and an Operator other than the IR(ME)R operator responsible for the actual irradiation of the patient confirms patient identification, then this individual must be clearly identified on the referral form as being responsible for this operator function.

3. Procedures

Staff performing the identification check should make every effort to maintain a patient's confidentiality. Where a patient indicates they are not comfortable to give information in public then they should be taken to a private location or asked to provide their identity by alternative means such as writing the details down.

3.1 Recording of patient identification check

The Operator confirming the patient's identity (ID) will be identified on the request form and RadIS. Where the patient does not directly identify themselves, the person confirming the patient's identification will be recorded.

For the C Arm it is recorded on request form and entered on Radis . In Dental the operator identifies themselves on the request form which stays with the rest of the clinical notes or directly in the notes. Anyone who cannot identify themselves is accompanied by someone eg parent / guardian / carer etc – this is recorded in the clinical notes.

3.2 Patient Identification Check

Refer to the Society of Radiographers” ‘pause and check’ procedure
https://www.sor.org/sites/default/files/sor_pause_check_a3.pdf

3.2.1 If the patient is conscious and able to confirm details:

The patient must be asked to positively identify themselves. Call in the patient by name. Ask the patient to TELL YOU all of the following:

- Name
- Address
- Date of Birth

3.2.2 If the patient is conscious but unable to confirm details:

The following must be checked against the patient identification (ID) band:

- Name
- Date of Birth
- Hospital Number

If the patient does not have an ID band then a member of nursing staff from the appropriate ward, who is familiar with the patient, must meet with the radiographer and patient to confirm the patient's identity and apply the ID band.

If there is a discrepancy between the ID band and the details on the referral form, the operator must seek further clarification of the incorrect details before proceeding.

3.2.3 If the patient is conscious but unable to confirm details due to language difficulties:

This scenario may apply to outpatients or patients referred from the Minor Injuries Department but not requiring admission, and therefore presenting without an ID band. In these circumstances, use must be made of the interpretation service available to PTHB, or the help of a family member/family friend who knows the patient well, to confirm the following:

- Patient's Name
- Patient's Address
- Patient's Date of Birth

If the x-ray examination request is from the Emergency Department, and of an urgent nature that will not allow time for the use of the interpretation service, or for a family member/family friend to arrive, an ID band must be put on the patient by the referring clinician prior to the x-ray examination proceeding. The procedure outlined in 3.2.2 should then be followed.

Care must be exercised here as it may be possible that the patient may not want a relative or friend to know that they are being examined.

3.2.4 If the patient is unconscious in the Emergency Department or MIU:

The following must be checked against the patient identification band:

- Name
- Date of Birth
- Hospital Number

If the identity of the patient is unknown the Hospital Number or 'Major Accident Number' must be used for identification.

EXAMINATIONS MUST NOT PROCEED UNLESS THERE IS AN ID BAND ON THE PATIENT.

3.2.5 If the patient is unconscious in Theatre:

(This scenario should only occur in an emergency situation and should not be used as the routine procedure for identification when using the MINI C-arm when the procedure in 3.2.1 should be followed)

The following must be checked against the patient identification band:

- Name
- Date of Birth
- Hospital Number

If the ID Band is hidden under theatre towels then the anaesthetist or operating surgeon must be asked by the radiographer to confirm the patient's identity by giving name, DOB and address or hospital number. The radiographer will remain the Operator for patient identification.

3.2.6 If the patient is unable to give their details but is accompanied by a parent/carer:

The examination must only proceed after the parent/carer has been asked to STATE the following information:

- Patient's name
- Patient's Address
- Patient's Date of Birth

3.2.7 If the patient is unable to give their details and is not accompanied by a parent/carer, e.g. patient has dementia:

- The examination must not proceed.
- A referral to 'Safeguarding' must be made.

3.2.8 If the patient is deaf or has speech difficulties:

Check the patient's details, in writing if necessary, asking them to write the following information:

- Name
- Address
- Date of Birth

3.2.9 If any demographic details do not match the details on the referral form:

If any aspects of the demographic details do not correspond, but the operator is confident that it is the correct patient e.g. one digit different in DOB or different address (old address), then the details can be changed. The referring ward/department should be informed of the change for future reference.

If all/most demographic details and clinical history are different then the patient should not be examined. The examination cannot proceed until the details are confirmed by the referrer.

3.2.10 Good Practice Points

In addition to the above, all attempts must be made to ensure that the examination requested by the referrer is consistent with the patient referred.

Details that must also be confirmed with the patient or other individuals e.g. parent or referring clinician, include:

- the area of examination
- clinical history on the referral form (as far as reasonably practicable)
- previous radiological examinations and reports (history available on RadIS)
- previous images available on PACS
- The patient should be asked about previous imaging and the operator should check that the timing of the examination is correct, where appropriate

3.3 Patient Handover

The identification procedures described above must be undertaken whenever a patient is initially identified, or collected by a member of staff, or transferred from the responsibility of one department to another.

It is undesirable that the radiological examination of a patient should be started by one radiographer and completed by another and this situation

should be avoided whenever possible. However, Radiology recognises that circumstances do arise when this is unavoidable such as hybrid imaging. If it is necessary for whatever reason, to hand over the completion of a radiological examination of a patient to another radiographer, the following procedure should be adopted:

- The radiographer who commenced the procedure should hand the request form to the radiographer who is to complete the examination. They should visibly identify the patient to the incoming radiographer and confirm that this is the patient named on the request form.
- They should show to the incoming radiographer any images that they have taken in order to avoid any unnecessary repeat images being taken by mistake.
- If they are dissatisfied with any of the images they have already taken, they should explain this to the incoming radiographer giving reasons and exposure factors in order that the incoming radiographer can repeat the view to a satisfactory standard.
- The outgoing radiographer should ensure that all the images that they have produced are correctly and legibly marked with patient details and anatomical markers.

4. References

SI (). The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.

STANDARD OPERATING PROCEDURE B

1 c Procedure for Establishing Patient Pregnancy Status Prior to Radiological Examination within Radiology

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Appendix 1 Adult Flow Chart for Establishing Pregnancy Status

Appendix 2 Under 18 Flow Chart for Establishing Pregnancy/LMP status

1. Introduction and Purpose

The purpose of this procedure is to minimise the risk of irradiating a foetus, thereby protecting the unborn child. The procedure explains how pregnancy checks should be made prior to medical ionising radiation exposure, where responsibility lies and how to deal with non-routine situations.

This procedure is written to comply with regulation 6 and Schedule 2.1(c) of the Ionising Radiation (Medical Exposure) Regulations [SI]. It is the responsibility of PTHB to ensure this procedure is in place and to ensure compliance by referrers, practitioners and operators.

2. Background & Scope

This procedure is related to all diagnostic exposures within PTHB and includes all radiological investigations involving ionising radiation.

National guidance has been used in formulating this procedure (see references).

Whenever practicable, alternative investigation techniques that do not involve ionising radiation should be considered before a decision is taken to use ionising radiation in patients with the capacity to bear children who are of reproductive age* (including children).

3. Definition of Child Bearing Age

This covers individuals with the capacity to bear children from 12 to 55 years of age. This age range therefore includes children who are defined as being “under the age of 18”, and as such they will require different consideration.

Consideration will also be given to patients outside the above age range who have a menstrual cycle e.g. children with precocious puberty.

4. Process

- The referrer is responsible for establishing the pregnancy status of each individual with the capacity to bear children who are of childbearing age (see section 3), where there will be irradiation of the abdomen or pelvic area* (see section 4).
- All appointment letters to patients will ask the patient to contact the department prior to attendance if they think they are or might be pregnant. <https://www.sor.org/news/new-version-popular-scor-pregnancy-poster>
- The operator will confirm that the referrer has provided sufficient information regarding pregnancy status on the request form / letter. Where this has not been undertaken by the referrer, or in the event of any difficulties when the irradiating operator checks the pregnancy status, the referrer may be contacted for clarification.

- The operator undertaking the x-ray exposure will be responsible for checking the pregnancy status of each individual with the capacity to bear children who are of childbearing age as they present for examination of the abdominal / pelvic area*. NB - In any situation the final responsibility for checking that the risk of pregnancy has been eliminated rests with the operator making the exposure. In all cases the operator questioning the patient about the likelihood of pregnancy must ensure that, whilst this process is being undertaken, the patient's privacy and dignity is maintained at all times.

4.1 Procedure if the patient is under 18

Individuals with the capacity to bear children between 16 – 18 years are considered capable of giving or withholding consent (i.e. capacity to understand hazards etc.). The decision whether to proceed is based on asking the patient about the possibility of pregnancy. Procedure - follow the adult procedure (see 4.2). and flowchart (Appendix 1).

Individuals with the capacity to bear children under 16 years – the decision as to whether to undertake the requested examination is based on the date of the last menstrual period i.e. LMP.

Procedure - ask if the child has started having menstrual periods, and if the answer is:

- NO – proceed with the examination.
- YES – ask for Last Menstrual Period date.
 - If within 28 days for low dose procedures (see definition), proceed with the examination, otherwise re-schedule to within 28 days of next cycle.
 - If within 10 days for high dose procedures, proceed with the examination, otherwise re-schedule to within 10 days of next cycle.

The irradiating operator writes the LMP in the 'Radiographer Comments' section of the request form and also on RADIS (see Appendix 2 Procedure Flow Chart).

NB: if a child (under 16) is found to be pregnant, the radiographer who is responsible for this Operator Function must contact Radiology Service Manager or Principal or Service Lead Radiographer regarding advice from Child Protection services (See Health Board Policy on Child Protection).

4.2 Adults – 18 years and above

The decision as to whether to undertake the requested examination is based on asking the patient about the possibility of pregnancy.

Procedure – The operator should ask the patient the following question: “Are you, or might you be, pregnant?”

Where the answer is a definite 'no' and the possibility is excluded, then proceed with the examination.

The patient & irradiating operator signs the appropriate part of the request form to indicate that the possibility of pregnancy has been excluded (and noted on RADIS – by "Preg.Exc").

If pregnancy cannot be excluded then take the following action:

Low dose examination* (see Section 5 for definition):

- Ascertain the onset date of the last menstrual period (LMP).
- If within 28 days – proceed with examination.
- If overdue – reschedule the examination to within 28 days of the onset of the next menstrual period.

High dose examination* (see Section 5 for definition):

- If within 10 days of the onset of the last menstrual period then proceed with the examination.
- If more than 10 days following the last period, reschedule the examination to the first 10 days of their next cycle.

4.3 Variance – Operating Theatres

The nurse completing the pre-anaesthetic checklist is responsible for checking pregnancy status as stated on the form. If there is a possibility of pregnancy, it is their responsibility for contacting the theatre team, prior to the patient leaving the ward, for advice. (If pregnancy is suspected then the patient should not leave the ward without advice from the theatre team).

The theatre team (practitioner & operator) effecting the exposure in the operating theatre is responsible for ensuring that they have:

- checked the pre anaesthetic checklist for completion of relevant areas.
- countersigned to say that they have checked the pre anaesthetic check list and that the patient is not pregnant (using the information given on the form, a copy if scanned and saved onto RADIS).

NOTE: Patients with the capacity to bear children arriving for operative procedures, already anaesthetised, without completed pregnancy checks, will constitute both a clinical incident & radiation incident, and the attending IR(ME)R practitioner & surgeon should discuss as to how to proceed in this scenario.

If pregnancy cannot be excluded at this late stage then the overriding principle will be patient safety whilst under anaesthetic, and if a decision is made to proceed with the exposure, then this should be recorded in the patient's notes & on RADIS. Should the patient subsequently be found to be pregnant at the time of exposure a foetal dose estimation should be performed and the surgeon should notify the patient of this fact. Completing a Datix form and notifying the Theatre Radiation Protection Supervisor is mandatory in this scenario.

5. Exceptional Circumstances

5.1 When pregnancy cannot be excluded (NON EMERGENCY)

In instances when pregnancy cannot be excluded e.g. the patient has an irregular menstrual cycle, the examination will not be able to proceed until negative pregnancy status has been confirmed. In such circumstances, a Health Board recommended pregnancy test will be utilised. The test will be conducted on the day of the proposed examination and the results will be interpreted by an individual who is deemed competent by BCUHB (e.g. radiologist, radiographer, registered radiology nurse). In interpreting the results of the pregnancy test, this individual becomes the operator responsible for ascertaining pregnancy status.

5.2 When pregnancy cannot be excluded (EMERGENCY)

If it is known that the patient is pregnant, the examination must not proceed until the urgency of the clinical circumstances have been taken into consideration. This may require further discussion with the referrer. It remains the responsibility of the practitioner in making the decision to justify or delay the examination.

If the patient has mental impairment or is unconscious in an emergency situation and pregnancy cannot be excluded the Practitioner must consider the risk/benefit situation of the presenting clinical circumstances in reaching their decision to justify and proceed with the examination.

Unless the urgency of medical treatment dictates otherwise the Practitioner must delay the radiographic examinations of the abdomen or pelvis until the pregnancy status is established as being negative. The practitioner must inform the referrer of their decision and make arrangements for conducting the examination at a later date, if still appropriate.

If the examination of the pelvis or abdomen has to proceed it can only be justified by the practitioner, i.e. the radiographer or radiologist who makes the ultimate decision to proceed with the examination. The responsibility cannot be transferred to the referring clinician.

Documentation of the practitioner and operator discussion must be completed on the request form and Radis. In addition, LMP where available and radiation dose details must also be recorded on Radis.

6. Definitions and Abbreviations

For definitions of referrer, practitioner and operator refer to the Ionising Radiation (Medical Exposure) Regulations .

Abdominal / Pelvic irradiation – is any examination which would cause direct irradiation of the pelvic area or abdomen by primary or secondary radiation. This is generally considered to be between mid-thigh to diaphragm. This

includes: conventional radiography; fluoroscopic examinations; CT and all Nuclear Medicine Examinations.

High Dose examinations:

- CT Abdomen; (Not upper abdomen or Thorax/Upper Abdomen.
- CT Abdomen & Pelvis
- CT Lumbar Spine,

Low Dose examination – all other examinations.

“Irradiating Operator” - an entitled BCULHB employee who finally initiates the exposure by: operating X-ray equipment by whatever means so that an X-ray tube is energised – or administers a radiopharmaceutical to a patient. In fluoroscopy – where a Radiologist initiates the exposure – the radiographer in charge of the list is responsible for ensuring that pregnancy has been excluded – however the Radiologist must confirm this prior to exposure.

7. Enforcement

Breaches in procedure should be reported to the Radiology Service Manager and in their absence to the Principal or Service Lead Radiographer.

Failure to comply with this procedure will lead to investigation by the Health Board, which may result in disciplinary action being taken.

8. Enquiries

Any enquiries regarding the operation of this procedure should be made to the Radiology Service Manager.

9. References

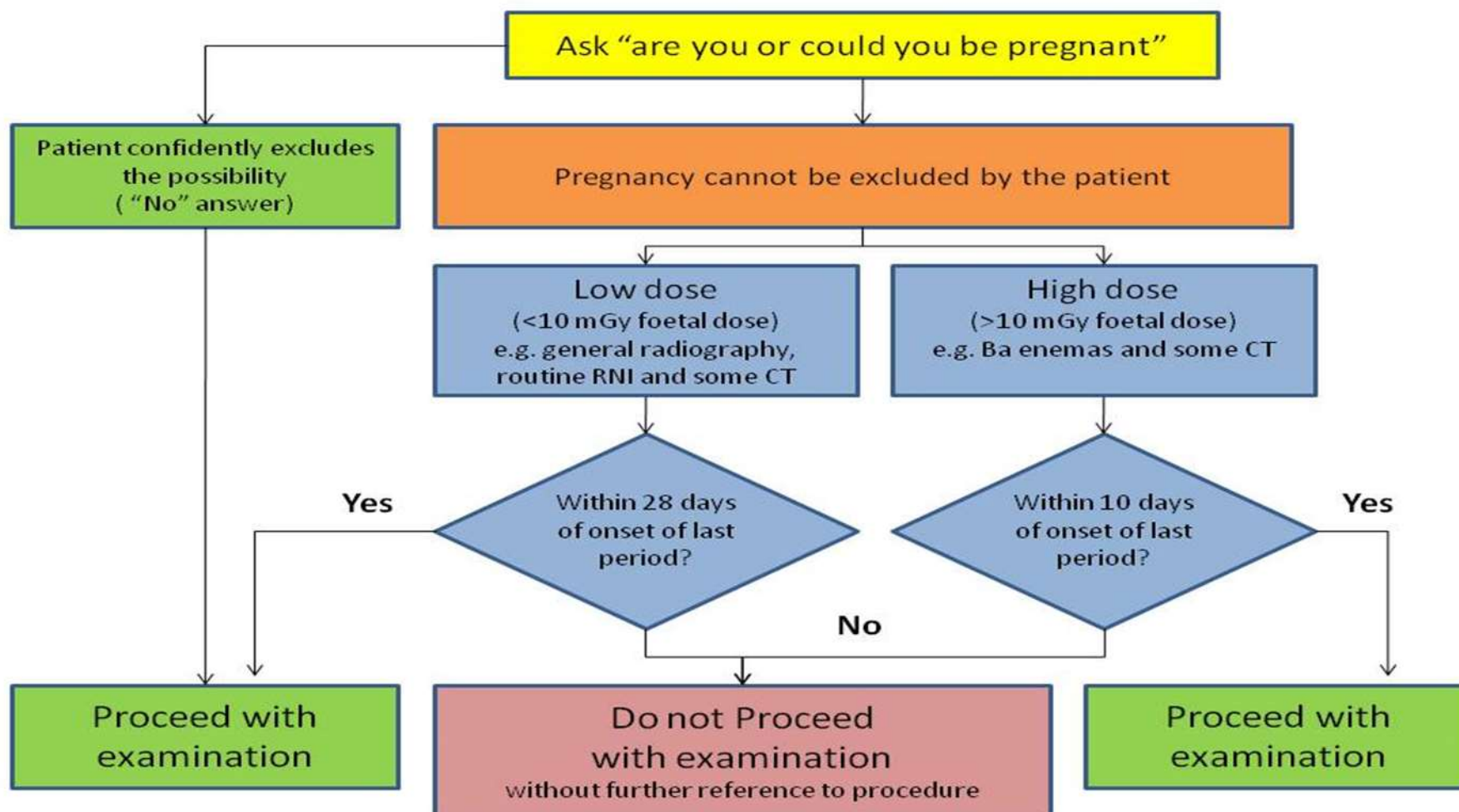
CoR 1995. The implications for radiographers of the Children Act 1989. College of Radiographers. <https://www.rcpch.ac.uk/resources/pre-procedure-pregnancy-checking-under-16s-guidance-clinicians>

CoR 2005. The child and the law: the roles and responsibilities of the radiographer. College of Radiographers.

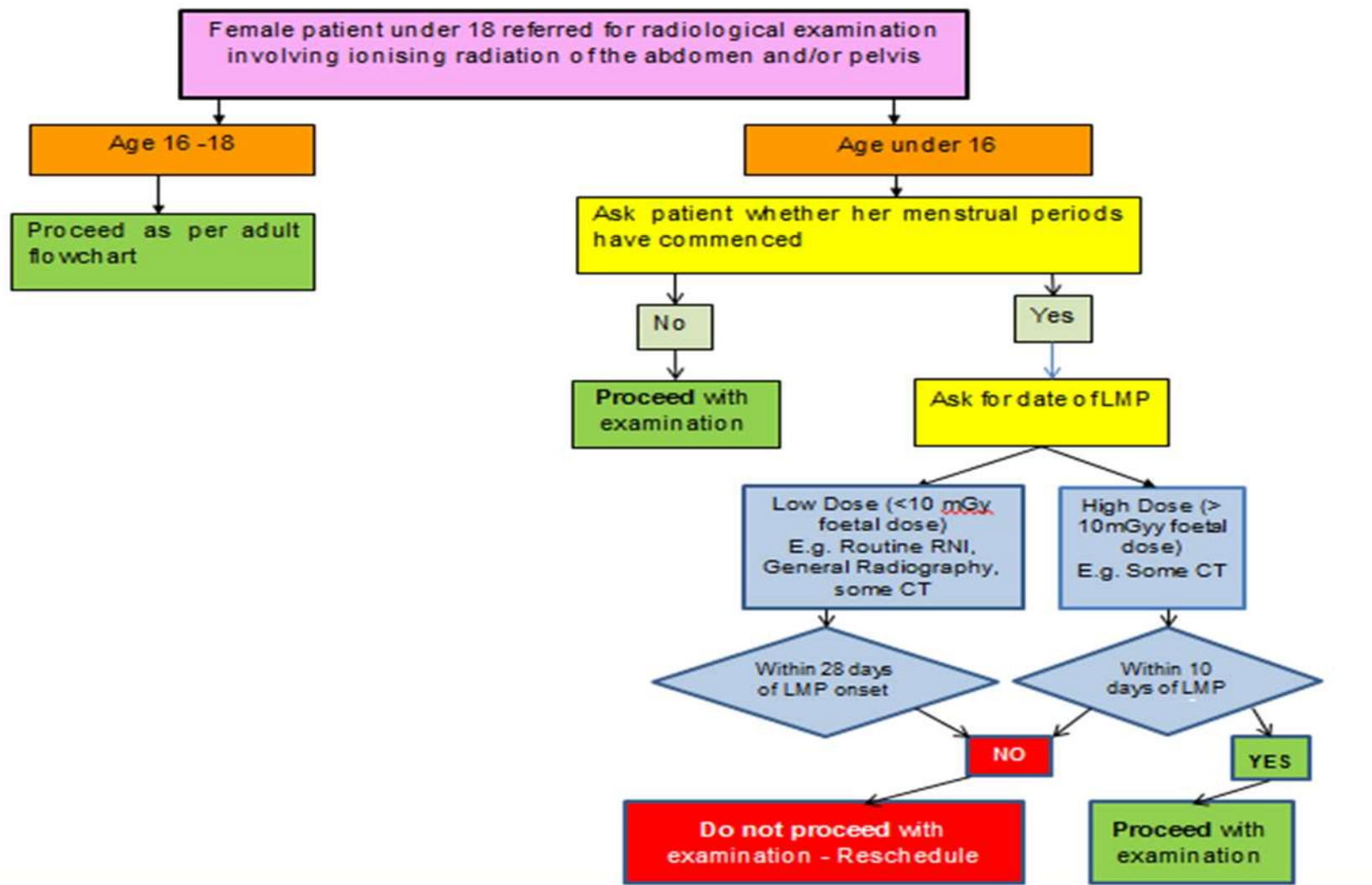
HPA 2009. Protection of pregnant patients during diagnostic medical exposures to ionising radiation. Advice from the Health Protection Agency, the Royal College of Radiologists and the College of Radiographers. Documents of the Health Protection Agency, Radiation, chemical and Environmental Hazards RCE-9.

SI (). The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.
https://www.bir.org.uk/media/416143/final_patient_shielding_guidance.r1.pdf

Appendix 1 – Adult Flow Chart for Establishing Pregnancy Status



Appendix 2: Patients Under 18 Flow Chart for Establishing Pregnancy/LMP Status



STANDARD OPERATING PROCEDURE C

IDENTIFICATION OF REFERRERS, PRACTITIONERS AND OPERATORS

Procedure required by IR(ME)R 17 Schedule 2 (1b) - Procedure for Entitlement and Assuring Competency of IR(ME)R Referrers, Practitioners and Operators

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Appendix 1 Identification of Practitioners and Operators

Appendix 2 Training requirements for Referrers, Practitioners and Operators

1. Introduction and Purpose

The Health Board Ionising Radiation Policy (PTHB/RAD002)) provides general advice on entitlement of staff to act as Referrers, Practitioners and Operators under the Ionising Radiation (Medical Exposure) Regulations [SI]

The purpose of this procedure is to identify staff entitled to act in these roles with reference to examinations being performed using ionising radiation within PTHB. This procedure also identifies the level of training required to act in each capacity.

In addition, this procedure also identifies who can refer patients for ionising radiation.

2. Scope

This procedure applies to all staff in Radiology/ dental employed by PTHB and those involved in performing procedures using the mini c-arm and relates to IRMER (SI) schedule 2.1(b).

3. Referrers

A Referrer is a healthcare professional* who is entitled to refer individuals for medical exposure to a Practitioner. (*A “registered health care professional” means 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.”)

Entitlement to refer is described in appendix 2 of the Ionising Radiation Protection Policy (RAD002)

For the purposes of the Ionising Radiation (Medical Exposure) Regulations the Referrers within PTHB are recognized as being:

- Medical Practitioners (registered and practicing) either primary or secondary care based within PTHB
- Dentists (registered and practicing)
- Named registered Non-Medical Referrers as described in the non-medical referrers to ionising radiation policy

All Referrers can be identified by means of their signature (hand written forms), or electronic signature (electronic referral system) on the request form. Best practise is for referrers to also include their professional registration number next to their signature.

3.1 Procedure for identifying Referrers

All request forms for radiological examinations must be assessed for the Referrer and cross-checked, as necessary, against the lists of those eligible to refer. Any discrepancies should be directed to the superintendent Radiographer.

Lists of eligible Referrers are held:

- on the Radiology Information System (RadIS) i.e. the actual Consultant, Dentist or GP in overall care of the patient;
- on HOWIS (GPs and GDPs) – WOD update this;
- on the PTHB intranet – i.e. current staffing list for the Health Board indicating consultants and clinicians within their teams;
- on the Radiology Non-Medical Referrer data base.

NB: Only the lead radiographers, have access to RadIS for changing the list of Referrers

3.2 Referrers and the radiology examinations they can request

In accordance with the statutory requirements of IR(ME)R, referrals for radiological examination will only be correctly 'justified' when sufficient patient details for the correct identification of the patient and relevant clinical information are supplied appropriate for the examination requested.

The referral guidelines will be the most current version of the Royal College of Radiologist referral guideline (i Refer) [RCR], available via Radiology intranet pages

For dental referral guidelines see references WDC 2011, EC 2004 AND FGDP 2013.

3.2.1 Clinicians employed by PTHB and PTHB primary care providers:

Diagnostic referrals – Medical Clinicians of all grades employed by PTHB are considered by Radiology to be eligible to refer patients for any type of radiology examination for diagnostic purposes providing that the request is in keeping with the referrers clinical experience, specialty and relevant protocols. See appendix 2.

Non-Medical Referrers will only be able to refer in accordance with their approved scope of practice.

Referral for non-medical imaging: see the non medical imaging procedure.

Research Referral: in accordance with the completed IR(ME)R trial documentation for the particular trial in question.

3.2.2 Community dental service/dentists:

Diagnostic referrals
Dental department
Periapicals
OPGs
Occlusals
PA and Lateral Cephs

General: Radiology will accept referrals from dentists for the following radiological examinations [WDC 2011]:
Chest, Lateral Soft Tissue, Neck, Para-nasal Sinuses, and T.M. Joints.

3.3 Procedure for identifying referrers outside PTHB

3.3.1 Regular referrals:

These are clinicians e.g. BCUHB, SaTH, South Meirionnydd, Robert Jones & Agnes Hunt, and visiting consultants who operate under an approved contract arrangement with PTHB.

3.3.2 Ad-hoc referrals:

Occasionally, clinicians from external healthcare organisations, who do not normally use this Health Board's Radiology facilities, will refer patients to Radiology. In these circumstances, referral is generally by letter to the lead radiographer or consultant radiologist. The radiology management information system requires a known referrer to be entered. For this ad hoc arrangement the lead radiographer or consultant radiologist to whom the referrer has written will be entered as the referrer. If there is no specific radiologist involved, the referrer will default to the Lead Radiographer. As far as the Practitioner is concerned, and for justification purposes, the referrer will be the clinician who has signed the letter. The patient letter will be scanned onto PACS.

Reports are returned to the original referrer.

All Referrers are informed of their legal responsibilities for providing accurate and relevant clinical information. This is done via:

- Induction Training for Health Board employed Medical Officers, when the organisation makes available to them referral guidelines for medical exposures
- Local training sessions led by a senior member of Radiology for approved non-medical referrers prior to formal entitlement in writing as described in the non-medical referrer procedure for the Health Board.
- Written communication with Referrers in both primary and secondary care on an annual basis.

3.3.3 Tertiary referrals:

Patients from PTHB are referred, as and when necessary, to consultant clinicians in tertiary centres for opinions and/or treatment. Whilst caring for these particular patients, it is possible that the tertiary consultants may require diagnostic radiological examinations. Whereas these examinations may be performed in the tertiary centre, it is also possible that, for the convenience of the patient, patients are referred back to their local hospital for their tests.

PTHB is willing to accept tertiary referrals from consultant clinicians for patients referred by this Health Board, although all such referrals must be

seen and justified by an entitled radiographer from PTHB. Any referrals in the form of a letter that have been typed and signed by a secretary, on the consultant's behalf, will not be accepted and must be returned to the referring clinician.

Tertiary referrals, which may be in the form of a letter or Radiology referral form, must contain all the information as detailed below:

- Patient name
- Patient address
- Patient date of birth
- Source of referral i.e. name and address of the referring consultant
- NHS or 'Private Patient'
- All relevant clinical details in order to facilitate justification including previous imaging
- Radiological examination required.
- Referrer's signature and date of referral.

All radiology reports resulting from tertiary referrals are sent to the tertiary referrer, at the address identified on the referral letter/form.

3.3.4 PPETCT referrals:

Referrals for PETCT will be made to the relevant health board under the WHSCC.

3.4 Non-Radiology referrers also acting as Practitioner and Operator

PTHB Radiology has recognised and agreed to named PTHB clinicians to act as Referrer, Practitioner and Operator for specific investigations.

Named Consultant Orthopaedic Surgeons and staff grade are entitled to refer for and perform orthopaedic fluoroscopy examinations using the mini C-arm once they have received a written letter of entitlement from the DoTH of PTHB. Where the mini C arm is being used by a consultant from another employer agreement to entitlement must be given by PTHB in writing.

The named clinicians will have undergone training which will include theory training regarding the statutory implications of IR(ME)R e.g. Derby Mini C-arm course together with signed off practical training on the mini c-arm from either the manufacturers applications specialist or a PTHB nominated key trainer for the Mini C-arm.

3.5 Legal Responsibilities

All Referrers are informed of their legal responsibilities for providing accurate and relevant clinical information.

- Local training sessions are led by a senior member of Radiology or supporting Health board for approved non-medical referrers and formal entitlement process as described in the non-medical referrer procedure for the Health Board.

- Written communication with Referrers in both primary and secondary care.
- Annual letter of entitlement to refer to radiology.

4. Practitioners and Operators

A *Practitioner* is a registered health care professional, who is entitled to take responsibility for an individual exposure. The primary functions of the Practitioner are to undertake the justification and authorisation of medical exposures. This requires the practitioner to have a full knowledge of the potential benefit and detriment associated with the exposure under consideration. The identified tasks and the practitioners' designation are tabulated within the entitlement Matrix.

An *Operator* is any person who is entitled to carry out practical aspects of the procedure of the medical exposure. There are many practical (operator) aspects of a radiological examination for each of which an Operator is responsible. There may also be several Operators involved in a single exposure. No overarching responsibility is held by another person. The identified tasks and the Operators' designation are tabulated within the entitlement Matrix.

For all radiological examinations, the Practitioner and Operator shall ensure that doses arising from the exposures are kept as low as reasonably practicable (ALARP). In doing so the operator shall select appropriate equipment and methods for the particular radiological examination(s) being performed

Those individuals entitled to act as practitioners/operators are described in appendix 1.

4.1 Recording of Practitioner and Operator

All practitioners and operators must be identified on the request form, and when appropriate also on RadIS.

The identification will be in the form of a signature or initials in the appropriate section on the request form

Dental

The operator identifies themselves on the request form which stays with the rest of the clinical notes or directly in the notes. Anyone who cannot identify themselves is accompanied by someone e.g. parent / guardian / carer etc – this is recorded in the clinical notes.

Mini c arm details on request form then entered on Radis.

4.2 When an Operator becomes a Practitioner for general radiography

Newly qualified radiographers will remain Operators for all categories of examinations for their period of induction following the commencement of

employment in PTHB. On commencement of employment the radiographer will receive a letter of entitlement to act as an Operator (Appendix 3). The radiographer will become an entitled practitioner when both the individual and management consider that sufficient training has been received, satisfactory levels of competence have been achieved and relevant experience has been gained to allow the individual to work in a single-handed capacity. A further letter of entitlement to act as a Practitioner will be issued (Appendix 4).

Newly appointed but experienced radiographers will be given Practitioner as well as Operator status on employment for those examinations that the appointing lead Radiographer deems within the scope and experience of that individual. Such radiographers will still participate in a departmental induction programme. An adapted version of the letter in appendix 3 will be issued.

At the end of induction, an informal meeting will be arranged to discuss any issues and a document signed by both parties that will indicate competence in the use of equipment.

4.3 When an Operator becomes a Practitioner for other examinations

Following the successful completion of appropriate training courses and individuals having had sufficient relevant practical experience, an informal meeting will be held between manager and the individual concerned. Similar discussions will take place to above and, again, documentation will be completed.

This document will be proof of the operator becoming a Practitioner and be filed in the individual's personal file.

Newly appointed but experienced radiographers will be given Practitioner as well as Operator status on employment for those examinations that the appointing lead radiographer deems within the scope and experience of that individual. Such radiographers will still participate in a departmental induction programme. An adapted version of the letter in appendix 3 will be issues.

Radiologists, radiographers and other personnel are named and identified for the various imaging modalities and examinations on operator and practitioner matrix including dental and Mini C arm Update of the matrix will be done by the Lead radiographer or professional head of radiographer. Radiography when any individual's entitlements are changed. Entitlements will be confirmed annually at the staff members PADR.

4.4 Entitlement following extension to practise

Radiology staff during the course of their employment may take on extended roles following a period of documented training e.g. radiographer reporting. Following successful completion of Radiology agreed training a certificate of entitlement to perform the extended role and associated IR(ME)R functions will be issued and the Radiology electronic entitlement matrix will be updated.

4.5 Entitlement Matrix

A copy of the entitlement letters will be kept in the staff members personnel file and at all stages the head of service will be responsible for ensuring that the IR(ME)R matrix is kept updated to reflect the entitlements.

The entitlement matrix is the master index of all entitlement functions.
For Radiology it is held on the M Drive, also on display in each department
For Community Dental Service
For Mini C-arm

Unless specified, a member of staff has the same entitlement rights when working on any other site providing they have received training on the specific equipment to be used.

5. Training records for Practitioners and Operators

IR(M)ER Reg 17 (4) states “The employer must keep and have available for inspection by the relevant enforcing authority an up-to-date record of all relevant training undertaken by all practitioners and operators engaged by the employer to carry out any exposures or any practical aspect of such exposures.....”

Within PTHB it is the responsibility of individual named Practitioners and Operators to maintain up to date appropriate training records. These records should reflect competence to perform medical exposures and carry out the practical aspects of an exposure.

Radiologists maintain individual records of their CPD. as required for re-registration with their professional body and appraisal.

Radiographers maintain individual CPD portfolios as a requirement for HCPC registration. Radiology also holds details of appropriate training and record of current HCPC registration.

Where IR(ME)R functions are performed by radiology staff in other health boards via an SLA e.g. Clinical evaluation by radiologists and reporting radiographers it is the responsibility of the employing health board to ensure staff have appropriate training and competencies and share these with PTHB on request.

Assistant Practitioners – Details of training undertaken at the recognised training establishment, together with copies of their successful qualifications are kept on file by Radiology together with details of other training undertaken. The examinations that can be undertaken by Assistant Practitioners are agreed at a local level in the form of scope of practise, details of which must be made readily available. The scope of practise will be further developed and reviewed in line with CPD and departmental needs.

More complex and uncooperative patients are referred to the supervising radiographer.

Student Radiographers – Students are responsible for maintaining their log books. The learning outcomes within the log books are shared with the radiographers. Assessments that are undertaken with the supervising radiographers (practical aspect) and the appointed Clinical Tutor (academic aspect and image quality) are recorded and kept on file. The clinical tutor is responsible for assigning students to examination rooms where the procedures undertaken are in keeping with their levels of competence. Student radiographers are not entitled to be classed as operators under the regulations

Non-radiology clinicians acting as image evaluating Operators – Whilst the maintaining of training records is the responsibility of the individual entitled to undertake this operator function, the departments/specialties employing such clinicians must maintain training records e.g. Minor injuries, primary care.

‘Other Operators’ – Non-radiology staff undertaking operator duties, e.g. nurses documenting the pregnancy status on pre-op check lists, must have adequate training to enable them to understand the requirement. Medical Physics Expert also a special type of operator under IRMER.

Radiology/Dental training records –

Radiology/Dental will retain the following training records:

- Confirmation of staff registration
- Copies of formal qualifications e.g. Degree and post graduate degree qualifications
- Training records for individual pieces of equipment
- Copies of extended role training documents.
- Copies of PADR – checklist of competencies and entitlements.
- Record of Statutory and mandatory training
- In-house update training

Orthopaedic Surgeons using the Mini C-arm

6. References

IPEM 2002. Medical and Dental Guidance Notes. Institute of Physics and Engineering in Medicine. York: IPEM.

EC 2004. European guidelines on radiation protection in dental radiology. The safe use of radiographs in dental practice. European Commission Radiation Protection Issue No.

136.http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/136_en.pdf

FGDP 2013. Selection criteria for dental radiography 3rd edition. Royal College of Surgeons, Faculty of General Dental Practice (UK)

<https://www.fgdp.org.uk/publication/selection-criteria-dental-radiography>.

RCR iRefer. Making the best use of clinical radiology. Royal College of Radiologists on-line referral guidelines. <http://guidelines.irefer.org.uk/>.

SI . The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.

WDC 2011. Advice on general dental practitioner direct access to imaging investigations undertaken by radiology departments providing dental radiography. Welsh Dental Committee.

Appendix 1 – Identification of Practitioners and Operators

Practitioner	Consultant radiologist	Radiographer	Entitled Orthopaedic consultant	Dental (need to be clear here)
CT	√			
Fluoroscopy MINI c arm	√		√	
General Radiography	√	√		
Mobile image intensifier and mobile radiography (theatre, ward and ED)	√	√		
Dental	√	√		√

Operator	Consultant radiologist	Radiographer	Radiographer with appropriate post graduate qualification or extended role entitlement or under training	Radiology Nurse	Assistant Practitioner	Radiology Assistant	Engineer & Application specialists	Medical Physics	Other Non radiology staff
CT	√	√	√	√		√	√	√	
Fluoroscopy	√	√	√	√		√	√	√	
General Radiography	√	√	√	√	√	√	√	√	
Mini C arm Mobile image intensifier	√	√	√	√		√	√	√	Appropriately entitled theatre staff
Ultrasound	√	√	√	√		√	√	√	
Mobile radiography	√	√	√			√	√	√	
Dental	√						√	√	Dental staff

Where assistant practitioners are supporting a radiographer in the same way as a radiographic assistant they hold the same operator functions.

Appendix 2 - Training requirements for Referrers, Practitioners and Operators

1. Referrers

Category	Required Level of Training	Scope of Referral
Medical Consultant or Specialist Trainee General practitioner	Appropriate Royal College Fellowship	All examination types and interventional radiology
Junior Doctor	Medical Degree	All diagnostic examinations and interventional radiology
Non Medical Referrers	Professional degree plus in-house training (Health Board Certificate)	Only those procedures laid down in the individuals' Scopes of practice and with written entitlement
General Dental Practitioners,	Dental/Medical Degree	All plain radiography of the head and jaw, and CXR, and lateral soft tissue neck
Sonographer	BSc Radiography/DCRr and Diploma in medical ultrasound	Abdomen Gynaecology DVT Testes

2. Practitioners

Category	Required Level of Training	Scope of Justification
Consultant Radiologists and Radiology, Specialist doctors in radiology, radiology Specialty trainees	FRCR For Specialty trainees must have completed part I of the FRCR	All examination types and interventional procedures
Radiographers	Radiography degree/diploma plus in-house training	All general radiographic examinations Also those examinations where specific entitlement has been given to a specific individual as identified on the entitlement matrix.
Entitled Orthopaedic surgeons	Member of Royal College of Surgeons + training as specified in this procedure	Mini c- arm

Dentists	Member of General Dental Council	Dental X-rays
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3. Operators

Category	Training Requirements	Practical Aspects
Radiographers	Radiography Degree/Diploma	Performing all general radiography
Radiographers with extended roles	Radiography Degree/Diploma + post graduate training in specified extension or completion of a radiology specified training programme.	Ultrasound, reporting or other extended scopes of practice.
Assistant Practitioners	Formal AP qualification	Performing general examinations as defined in local division scope of practice.
Consultant Radiologists and Radiology, Specialist doctors in radiology, radiology Speciality trainees	FRCR or Radiography degree.	Clinical evaluation, ID, Pregnancy status, specialist procedures e.g. IR, biopsies etc.
Orthopaedic consultant	FRCS - + mini c arm training course.	Mini -arm
Radiographers	Radiography degree/Diploma plus in-house training.	In-house QC on X-ray equipment.
Medical Physics Staff	Training provided by Medical Physics department of supporting HB.	QC (including testing before use and routine level B tests).
Radiographers and Imaging Department Assistants	In-house training.	Patient care, image processing and QC.
Dentists		All IR(ME)R aspects associated with dental radiography.

Appendix 3 – Entitlement letter for Newly Qualified Radiographer

Entitlement during Induction - Operator Only

I _____, radiographer, have completed and passed my academic training and am registered as a Radiographer with the HCPC and am ready to commence my role as Radiographer within Radiology of PTHB.

During induction - I (the radiographer) will be unable to act as a practitioner (justify requests); this role must be performed by Radiographers who have already completed their induction. I acknowledge that my level of entitlement is documented in the IRMER Matrix as detailed below.

- Operator for all plain film examinations
- Operator for dental examinations
- Operator for Mobiles
- Operator for Pregnancy status
- Operator for ID
- Operator for fluoroscopy (e.g barium studies)
- Operator for patient care
- Operator for QA of equipment
- Operator for image processing

Signed Radiographer:

Date:

The entitlement Matrix has been updated to reflect these changes.

Signed:

Role:

Date:

Appendix 4 – Entitlement letter for newly qualified radiographer on completion of induction

Entitlement upon completion of Induction

Upon completion of the departmental induction, and agreement that a satisfactory level of knowledge has been obtained, the radiographer will be able to act as an operator and a practitioner as detailed in the IRMER Entitlement Matrix. I acknowledge that my level of entitlement is documented in the IRMER Matrix as detailed below:

- Operator for all plain film examinations
- Operator for dental examinations
- Operator for Mobiles
- Operator for Pregnancy status
- Operator for ID
- Operator for fluoroscopy (e.g barium studies)
- Operator for patient care
- Operator for QA of equipment
- Operator for image processing
- Practitioner for all plain film examinations
- Practitioner for dental examinations
- Practitioner for Mobiles

Signed Radiographer:

Date:

I acknowledge that the radiographer listed above has completed and passed their academic training, are registered with the HCPC and has completed the Departmental Induction, and they are now entitled to act as a Practitioner for those examinations listed within the IR(ME)R Entitlement matrix. The entitlement Matrix has been updated to reflect these changes.

Signed:

Role:

Date:

References

IPEM (2002). Medical and Dental Guidance Notes. Institute of Physics and Engineering in Medicine. York: IPEM

SI (). The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.

Appendix 5 - Competency of Expert Advisers

IR(ME)R requires Medical Physics Experts (MPEs) to be recognised by the Department of Health and Social Care (DHSC). DHSC has appointed RPA2000 to act as the authorised Assessing Body for MPE recognition. Any person wishing to act as a MPE must gain a Certificate of Competence from RPA2000 or be on the list of MPEs that have been entitled to act in that capacity by an employer under the previous regulations, IR(ME)R2000, between 1st July and 31st December 2017.

The Health Board is responsible for assessing an individual's suitability for a specific MPE role and for appointing them. A local list of individuals able to act as MPEs will be kept by the specialist area manager within the Medical Physics Service supporting the Health Board via SLA.

Tasks	Staff group (specialist area of expertise)	Summary of expected Level of training and experience
As defined in IR(ME)R 14(2)(3)4)	Clinical Scientist (Diagnostic Radiology)	HCPC registration plus Certificate of competence to act as MPE from RPA2000 OR On national list of MPEs that have been entitled to act as MPE by an employer between 1 July and 31 December 2017

STANDARD OPERATING PROCEDURE D.

MAKING A REFERRAL

Scope: Referrers.

Purpose / Objective

The Employer considers a referral for a medical exposure to be a request for a medical opinion. It is important that details of the individual to be exposed and the referrer are clearly stated. It is a legal requirement that the referral contains sufficient relevant medical data for the correct justification of the exposure.

All medically and dentally qualified staff employed by the Health Board are entitled to make a referral. Non-medical staff are identified in local policies. Referrals from outside the Health Board can only be made by medically and dentally qualified persons.

Referrals can be made by completing a written request form. They can be discussed in advance by telephone or in person, but it is still necessary to complete a request form in full. Where a medical exposure is an inherent part of a procedure, the request for that procedure will be taken as a referral for a medical exposure.

The Referrer

The Referrer who signs the form or referral letter is legally accountable for the accuracy and adequacy of the information. Such information must be sufficient enough to allow the Practitioner to justify the exposure.

Referrers must:

- Never complete a request form UNLESS the patient identification details have been entered first either in writing or by means of a pre-printed label.
- Sign the request form only after patient I.D. details have been completed.
- Complete the request form, legibly and accurately.
- Identify any referrals that are part of a research protocol agreed by LREC.

The Referral

Refer to the Referrer Pause Check from SOR

https://www.sor.org/sites/default/files/pause_check_irmer_referrers_a4.pdf

The request form must clearly identify the person to be exposed. This information will be used to verify the identity of the individual prior to the exposure. Suitable details should include the patient's full name rather than a "pet" name, date of birth and address.

If the referral does not adequately identify the individual or the request form is illegible, it will be returned to the referrer. The reason for return will be clearly stated. The x-ray department will carry out regular audit to identify and manage any problems. An example of the explanation form used to return x-ray forms and the policy for incorrectly completed X-ray request forms are attached.

The referral must include any medical data relevant to the medical question being posed by the referrer. This is a legal responsibility placed on the referrer by IR(ME)R and will enable the practitioner to decide whether there is sufficient net benefit and to consider the most appropriate technique (including non-radiation technique) to meet the referrers objective.

The Employer has endorsed the use of the RCR Referral Guidelines www.irefer.org website. Local criteria may also be available. Referrers should make use of this information and are encouraged to contact the practitioner directly in cases of uncertainty. These guidelines do not include dental exposures.

If the individual being referred is a female of childbearing age, pregnancy is considered to be relevant medical data. The referrer should therefore take steps to ascertain whether pregnancy is likely and include details of the response on the request form. Referrals with insufficient medical data will be returned to the referrer.

The referral must clearly identify the referrer. If this is not clear, or if there is doubt that the person named as the referrer on the request form has not personally verified the patient and medical details on the form, the request will be returned to the named referrer.

Intra oral and extra oral radiograph referrals taken by the dental practitioner/nurse follow the guidelines issued by the Faculty of General Dental Practitioners (UK) 2018 and FGDP(UK)'s Selection Criteria for Dental Radiography (<https://www.fgdp.org.uk/guidance-standards/selection-criteria-dental-radiography>). The dental practitioner will record the referral details in the patient's clinical dental record.

A log of returned referrals is maintained by the Radiography Team Leader / Head of Department and checked at least monthly for trends or significant themes that require further intervention / attention.

Urgent referrals via telephone or fax

This applies only to urgent x-ray referrals for plain film radiography.

- Patients for routine referrals will be sent postal appointments or contacted by telephone once the x-ray requests have been justified. Urgent ultrasound examinations must be agreed with the Consultant Radiologist.
- Following a visit to the G.P. practice where an urgent x-ray is considered necessary, patients can either be given the x-ray request form and asked to telephone the x-ray department to arrange a mutually convenient time for the x-ray examinations to be performed, or this can be organised by the receptionist before the patient leaves the G.P. surgery.

- Patients will be informed that on arrival in the x-ray department, should the radiographer not be in a position to justify the request, the examination will not take place until further clarification has been sought from the referrer or consultant radiologist. This may require re-scheduling the appointment.
- On arrival identification details will be checked as stated in Standard Operating Procedure A.
- Faxed requests will be accepted if the referral is urgent. Original forms must either accompany the patient or be sent to the x-ray department before the appointment date. Patients will not be seen without the original request form. (w/telref)

Incorrectly completed X-ray forms

This affects all x-ray request forms that are incorrectly completed in accordance with the IR(ME)R Standard Operating Procedures for the departments of Clinical Radiology.

X-ray forms received from the wards, out-patient clinics and minor injury units which are not correctly completed will be returned with a form indicating the problem. The clinician who amends the form must sign the change and if different from the original referrer, then becomes the referrer.

X-ray forms not correctly completed from GP and dental practices for routine appointments will be returned to the referring clinician with a form indicating the problem.

- If the patient is in the department, the referring clinician will be contacted by telephone. A fax with the corrected details may be accepted (refer to local policy).
- If the referrer cannot be contacted and there is only one discrepancy in the patients' details i.e. 30/4/19 instead of 30/4/18, the operator may continue with the examination as long as there is no doubt over the identification of the patient or the examination to be undertaken. The radiographer acting as practitioner will correct and initial the change. If any doubt exists, an explanation will be given to the patient as to why the examination cannot take place and the form returned to the referrer.
- A completely wrong date of birth and differences between right and left will be considered major discrepancies and must be returned to the referring clinician for verification.
- Where routine appointments are made over the telephone, when possible the details will be checked with the patient. If there are any discrepancies the patient will be referred back to the GP/dental surgery before attending their x-ray appointment.

Incidents considered to be near misses will be recorded on the Teaching Health Board Incident Form Datix dif 1.



X RAY DEPARTMENT

Tel: _____

Date: _____ **Referring GP:** _____

Patient's Name: _____

You have requested an imaging investigation on this patient. We are unable to accept this request and are returning the form because:

- Inadequate/illegible patient details for unique identification of the patient. (IR(ME)R Standard Operating Procedure A)
- Incorrect patient details
- Duplicate request
- Inadequate/illegible clinical information.
- The investigation requested appears inappropriate for the clinical information supplied.
- Please discuss with a radiologist.
- Patient has cancelled - please indicate and return request form if still required.
- Patient has deferred appointment several times - please re-refer if still required.
- Patient has been discharged from the ward - please indicate and return request form if still required.
- Is not compatible with R.C.R. guidelines.
- Please see comments from Consultant Radiologist

STANDARD OPERATING PROCEDURE E.

**PROCEDURE FOR NON-MEDICAL IMAGING EXPOSURES (INC MEDICO-
LEGAL EXPOSURES/ CAT 11 HEALTH SCREENING**

**IR(ME)R regulations Schedule 2 (1m) - Procedure for Non-medical Imaging
Exposures**

Contents

- 1. Introduction and purpose**
- 2. Scope**
- 3. Responsibility**
- 4. Practice**
- 5. DRLs**
- 6. References**

1. Introduction and Purpose

To identify considerations when carrying out 'non-medical' imaging exposures.

IR(ME)R defines 'non-medical' imaging exposures as: 'any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed' where medical radiological equipment is used.

2. Scope

This procedure applies to all 'non-medical' imaging exposures" including:

- Health Assessment for employment purposes.
- Health Assessment for immigration purposes.
- Health Assessment for insurance purposes.
- Identification of concealed objects within human body where there is no health risk concern.
- Age assessment.
- 'Suspected Inflicted Injury' – not performed in PTHB.
- Sport (to aid decisions on: selection, training, nutrition, i.e. not medical care).
- Physical development of children (with a view to a career in sport, dancing etc.).

3. Responsibility

It is the responsibility of the IR(ME)R Practitioner to make it clear on the request form that the exposure is required for "non-medical' imaging exposures by annotating the request form.

It is the responsibility of the Practitioner to justify all 'non-medical' imaging exposures. Assistance with items to be considered in the justification process for non-medical imaging can be found in IAEA General Safety Guide GSG-5 [IAEA 2014]

4. Practice

4.1 General

- 4.1.1 No 'non-medical' imaging exposures should be performed unless they can be justified. In such cases, the benefits maybe financial or social rather than for the health of the individual being exposed.
- 4.1.2 There should be sufficient information from the referrer to allow justification.
- 4.1.3 The procedure should only be justified if it is not readily possible to use alternative techniques involving no or less exposure to ionising radiation.

- 4.1.4 Checks should be made to determine if this medical exposure has already been performed during the routine clinical management of the patient, to avoid unnecessary repeat exposures.
- 4.1.5 The request card will be accepted as the standard radiology request form or a letter from the medical advisor or a solicitor on behalf of the medical advisor.
- 4.1.6 Once justified and authorised, ‘non-medical’ imaging exposures should be performed as for other standard medical exposures, i.e. taking care to keep doses as low as reasonably practicable, within the diagnostic reference level, noting the exposure settings or administered activity for the calculation of effective dose, and making a clinical evaluation of the outcome of the exposure.

Table 1: Current ‘Non-Medical’ Imaging Procedures Performed in Powys

Category	Referrer	Practitioner	Operator(s)
Pneumoconiosis Chest X-rays	Medical Referrer with Health Board entitlement	Radiologist	Radiographer, Radiographic Assistant Radiologist
Emigration Chest X-rays	Medical Referrer with Health Board entitlement	Radiologist	Radiographer Radiographic Assistant Radiologist
Identification of concealed objects within human body where there is no health risk concern.	Police Surgeon Medical Referrer with Health Board entitlement	Radiologist	Radiographer Radiographic Assistant Radiologist
Category II	Medical Referrer with Health Board entitlement	Radiologist	Radiographer Radiographic Assistant Radiologist
Other Non Medical- Imaging exposures – Insurance, employment, immigration	Medical Referrer with Health Board entitlement or medical advisor following discussion with a consultant radiologist	Radiologist	Radiographer Radiographic Assistant Radiologist
Bone-Age Assessment	Entitled Paediatrician	Radiographer/Radi ologist	Radiographer Radiologist

5. DRLs

IR(ME)R Guidance states 'Diagnostic Reference Levels' (DRLs) for 'non-medical' imaging must be established where such exposures are undertaken on a routine basis. None of the procedures listed in Table 1 are currently performed frequently enough to allow accurate derivation of a DRL.

6. References

SI 20017. The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.

IAEA 2014. Justification of practices, including non-medical human imaging. International Atomic Energy Agency, Safety Standards Series, General Safety Guide GSG-5. Vienna: IAEA. <https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1650web-23654722.pdf>.

STANDARD OPERATING PROCEDURE F

JUSTIFICATION / AUTHORISATION OF A MEDICAL EXPOSURE

Scope: Referrers, Operators and Practitioners.

Purpose / Objective

IR(ME)R requires every individual medical exposure to be justified and authorised in advance.

With every medical exposure there is an inherent detriment associated with the potential for harm caused by the interaction of ionising radiation with tissue. The justification process must assess this detriment and balance it against the perceived benefits to the individual being exposed, or to society, if the medical exposure is carried out. There should clearly be a net benefit.

In some cases there may be alternative procedures carrying a smaller risk to the individual which might result in the same beneficial outcome. These alternatives must be considered as part of the justification process in order to ensure that the medical exposure carries sufficient net benefit.

In the majority of cases the practitioner justifying the exposure is not the referrer. The practitioner must therefore rely on medical data supplied by the referrer to establish the reason for the exposure and the benefits to be gained. The practitioner should consider the available medical procedures which answer the objectives of the referrer and select that procedure which maximises the benefit without compromising the objectives.

The practitioner has an important role in reducing unnecessary radiation exposure and, therefore, has the right and responsibility to refuse to undertake exposures that cannot be justified.

If it is not possible, with the medical data available, to come to a conclusion on the justification, the practitioner should discuss with the referrer or return the request with the explanation form (see attachment to Standard Operating Procedure D).

If doubt persists, the practitioner should discuss with a consultant radiologist. Information on the radiation detriment associated with medical exposures will have been gained through the practitioner's training. More specific local information regarding standard exposures will be available from Protocols for each procedure.

Justification

When justifying a medical exposure, consideration should be given to:

- The objectives of the exposure and the characteristics of the individual.
- The direct health benefit to the individual and society.
- The individual detriment the exposure may cause.

- The benefits and risks of alternative techniques which may meet the objectives with less or no detriment.

The following matters demand special attention:

- Exposures on medico-legal grounds.
- Exposures with no direct health benefit to the individual being exposed.
- Exposure of females who are, or may be pregnant.
- Paediatrics

Authorisation

Having justified an exposure the request should be authorised before being carried out. This will be recorded as the practitioners' signature on the request form. If additional clinical information comes to light indicating that the exposure cannot be justified another practitioner may cancel this authority.

In cases where the referrer is the same person as the practitioner/operator i.e. Dental practitioners, justification still needs to be performed and recorded but the same person may do this.

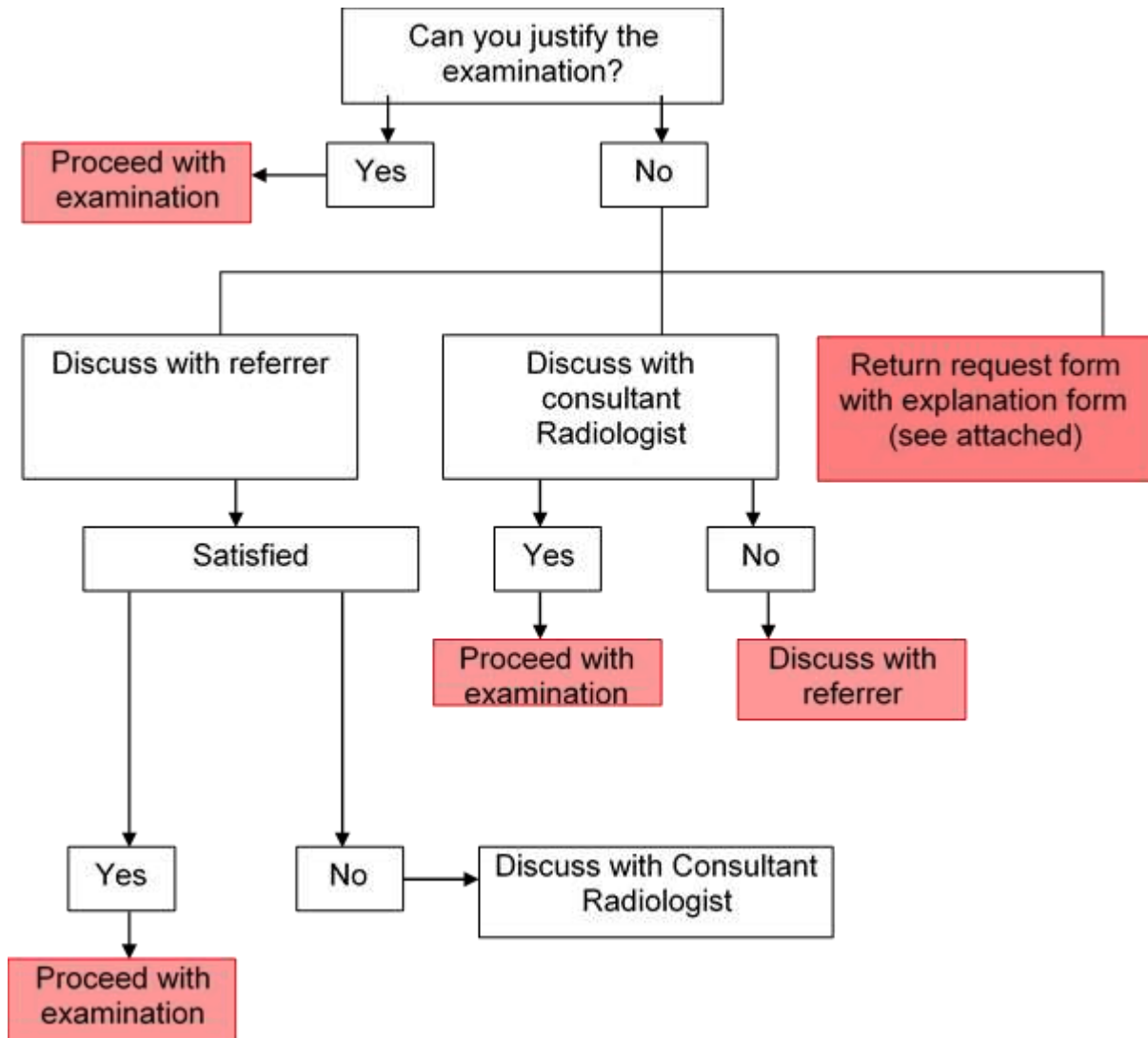
All qualified radiographers in the Health Board are senior grades and have been adequately trained and entitled to act as practitioners and operators for all plain Radiography of the axial and appendicular skeleton, plus chest and abdomen x-rays, also Plain OPT and lateral cephs at Brecon and Llandrindod Wells.

It is expected that they will use their professional knowledge and experience, together with an awareness of best practice advocated nationally and locally, to determine whether the medical exposure proposed is the most appropriate for the individual presented.

In reaching this decision they must take full account of the clinical details given and must refer the request back if it is deemed that there is insufficient detail.

Department of Clinical Radiology

Justification of Exposure Flowchart



STANDARD OPERATING PROCEDURE G

EVALUATION OF EXPOSURE

Scope: Referrers and Practitioners.

Purpose / Objective

The Employer considers that a referral for radiology is a request for a medical opinion. It is important that an evaluation of the outcome of an examination involving ionising radiation is recorded and communicated to the referrer or other relevant staff in a timely manner to facilitate the appropriate clinical management of the patient.

Clinical evaluation and reporting process

If it is known prior to the exposure that no clinical evaluation will occur, then the exposure will not be justified and cannot lawfully take place.

Other than images produced in examinations and procedures listed below all images are formally reported by consultant radiologists, specialist radiology registrars or reporting radiographers. Image evaluation is an 'operator' function.

Procedures and examinations that are not generally issued with formal reports by Radiology Departments with whom there is an SLA include:

(i) Fluoroscopic Images

Orthopaedic operative procedures using mini c-arm

(ii) Radiographic Images / Prints

Dental (OPG, Lat Ceph, Periapical)

For images produced in (i) and (ii) above it is deemed that the referring clinicians are competent to undertake the formal evaluation of the images themselves and record their own radiological reports in the patient's case notes or, where applicable on the referral form, with an authorised signature.

Clinicians, who are entitled to do this, are regarded as Operators under IRMER. Where the Clinician is not a member of the SLA identified Radiology Department, the employing specialty is responsible for ensuring the clinician is appropriately trained and training records are maintained. Training records must be available to IR(ME)R inspectors if requested. Audit will be carried out at least annually by the Radiation Protection Supervisor to ensure compliance and reported to the Radiation Protection Committee.

Should the referring clinician involved in any of the procedures listed in (i) and (ii) require a formal radiological opinion, this will be facilitated by the radiology department following the evaluation of appropriate images.

Clinicians evaluating images and acting on their findings to clinically manage their patients prior to the availability of a formal report must also ensure that they are

appropriately trained and that training records are maintained and available for inspection.

In the event of an operator becoming aware of a life-threatening condition following viewing of an image, e.g. pneumothorax, pneumoperitoneum, the operator has a duty of care to inform the referring clinician immediately.

All radiology generated reports are available on the RIS and PACS systems. A printed copy of all reports generated by radiologists, SPRs and reporting radiographers is dispatched to the Referrer for inclusion in the patient's medical notes.

It is the referring clinician's responsibility to ensure they have appropriate systems in place to comply with the NPSA 16 Failure to Act Alert (NPSA 2007).

STANDARD OPERATING PROCEDURE H

ASSESSMENT OF PATIENT DOSE

IR(ME)R 17 Schedule 2(1e) – Procedure for recording patient dose as appropriate for examinations using ionising Radiation

Contents

1. Introduction and purpose

2. Scope

3. Procedure

3.1 Procedure where measuring device or dose display is available

3.2 Procedure where measuring device is not available

3.3 Procedure for recording dose when there is a known pregnancy or pregnancy status is unknown and there is a clinical urgency to proceed when imaging the abdomen and pelvis.

3.4 Procedure for imaging in Suspected Inflicted Injury (previously NAI)

4. Definitions and Abbreviations

5. References

1. Introduction and Purpose

The purpose of this procedure is to ensure that the radiation dose for each medical exposure is recorded accurately and in a format that will allow this information to be retrieved if at any time it is required in the future.

For issues regarding the carrying out and recording of an evaluation for each medical exposure, see appropriate IR(ME)R procedure.

2. Scope

This procedure applies to all Radiographers, Radiologists and Radiology Assistant Practitioners, dentists employed by PTHB and any IR(ME)R entitled users of the mini C-arm relates to IRMER (SI) schedule2. 1(e)

3. Procedure

3.1 Procedure where measuring device or dose display is available

- 3.1.1 The Health Board is responsible for providing and maintaining appropriate recording devices.
- 3.1.2 Medical Physics service via SLA are responsible for ensuring regular Quality Assurance is performed on the measuring device at appropriate intervals. The results of this regular quality assurance should be readily available in the department.
- 3.1.3 The operator should ensure that the measuring device is switched on.
- 3.1.4 The operator should ensure that this measuring device is reset prior to each patient and on completion of examination.
- 3.1.5 On completion of the examination, it is the operator's responsibility to ensure the appropriate parameters (see Table 1 below) are recorded. Care needs to be taken to ensure that the correct dosage unit is selected from the available range in the Radiology Information System (RadIS) for radiology procedures. This will facilitate work on patient dose optimisation. The operator may also record the dose information on the request card. For dental services the dose will be recorded.
For Mini C-arm – record patient dose and screening time

Table 1 – Dose quantities to be recorded for each modality

Modality	Parameter(s) to record	Where record is to be kept
Radiography	Dose Area Product (DAP)	RadIS
Mobile X-ray	Dose Area Product (DAP)	RadIS
Dental Radiography		
Mini C-arm	DAP and screening time	RadIS

3.2 Procedure where measuring device is not available

In the absence or malfunction of a dose recording device, the relevant exposure factors for each individual exposure should be recorded. E.g. screening time, frame rate, kV, mAs.

3.3 Procedure for recording dose when there is a known pregnancy and there is a clinical urgency to proceed when imaging the abdomen and pelvis. Or when post procedure it is identified that the patient was pregnant at the time of imaging

Dose should be recorded after each individual exposure per body area and all exposure factors must be recorded in accordance with 3.1 . Medical physics must be informed so that a risk estimate for the foetus can be calculated.

3.4 Procedure for imaging in Suspected Inflicted Injury (previously NAI)

PTHB do not offer this service and requests for this imaging must be referred to the supporting HB.

4. Definitions and Abbreviations

For definitions of Referrer, Practitioner and Operator, refer to the Ionising Radiation (Medical Exposures) Regulations (SI)

DAP Dose area product.

mA Tube current

mAs Product of tube current and exposure time

Measuring device An instrument for measuring the amount of radiation produced e.g. dose area product meter

RadIS Radiology Management Information System

kV Tube potential

5. References

IPEM (2002). Medical and Dental Guidance Notes. Institute of Physics and Engineering in Medicine. York: IPEM

SI (). The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.

STANDARD OPERATING PROCEDURE I

MONITORING DIAGNOSTIC REFERENCE LEVELS (DRLS)

IR(ME)R Schedules 2(f) and 2(g) – Procedure for Diagnostic Reference Levels

Scope: All Operators, RPS, Head of Community Dentistry, Radiography General Manager, Medical Physics Expert, Director of Therapy and Health Sciences.

1. Introduction

Current UK legislation, [SI] requires that for typical medical X-ray examinations, Diagnostic Reference Levels, (DRLs) are established and regularly reviewed by the employer. These levels are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. This document describes how this will be carried out within PTHB.

DRLs are defined as guides to the doses delivered to groups of standard sized patients or phantoms for typical medical X-ray examinations. They are not intended to be used on a patient by patient basis.

Public Health England, PHE (formerly NRPB & HPA) maintains the National Patient Dose Database which is a receptacle for doses submitted from UK wide radiology departments. This database is reviewed by PHE every five years and the 75th percentile dose (of examinations with sufficient records to make the result statistically significant) is recommended as the National Reference Dose. This value will then be formally adopted as the National Diagnostic Reference Level (NDRL) by the Department of Health (DoH). In , the DoH expanded their criteria to allow other well conducted studies to provide the basis for NDRLs. The current list of NDRLs is located on the DoH website (<https://www.gov.uk/government/publications/ diagnostic-radiology-nationaldiagnostic-reference-levels-ndrls/national-diagnostic-reference-levels-ndrls>)

It is important that the organisation has ownership of the protocols in use and hence of the associated level of dose. A method of achieving this is by the establishment of Local DRLs. These levels should be established for a range of examinations to fully reflect the overall clinical workload of the organisation. They should be established such that there is at least one local DRL per item of X-ray equipment which significantly contributes to the organisations clinical workload. They should be set so as to fully represent the organisation's operators. They are only required for examinations for which dose audit is practical based on patient numbers and ease of data collection. They may be defined in terms of dose area product, dose length product, exposure time or any other suitable metric as determined by the Medical Physics Expert, MPE.

2. Scope

This procedure is intended to satisfy the requirements of Ionising Radiation (Medical Exposure) Regulations, Schedules 2(f) and 2(g) in conjunction with Procedure RAD03.

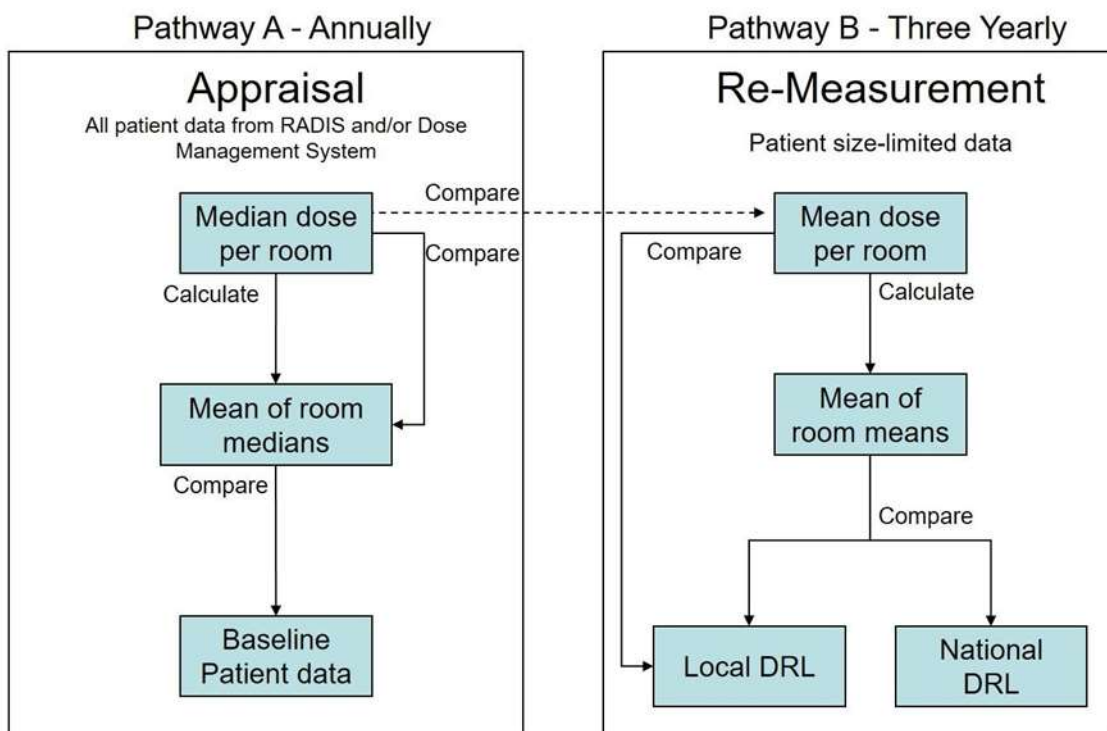
The procedure is aimed at Clinical Radiology staff and Medical Physics Experts, community Dental Service Officers and Operators and practitioners for the |Mini C-arm.

3. Establishing and Maintaining Diagnostic Reference Levels

3.1 DRL Selection and Methods

Each geographical area within PTHB will maintain independent data, however cross-comparisons will be made where applicable. The Superintendent radiographers and head of dental service will be the DRL leads. The examinations considered will be determined by the MPE / DRL leads based upon relevant clinical workload.

Data for X-ray examinations will be collected using two methods.



The data collection will be carried out for locally defined examinations and x-ray facilities, including radiographic and fluoroscopic procedures using the mini c-arm and dental imaging.

It is the responsibility of the designated leads for DRLs to manage the data collection.

Annually, data will be extracted from the radiology information system (RADIS) and/or the Dose Management System (DMS) and collated by the

Medical physics expert (MPE). This will enable ongoing comparisons of doses delivered to the typical patient demographic for individual x-ray facilities and examinations.

Additionally, on three year rolling programmes, data will be collected to enable comparisons to the relevant National DRLs currently in force. Fluoroscopy procedures will be monitored by recording a minimum of 5 representative patients per operator per fluorographic installation. Other modalities will involve recording of imaging parameters for typically a minimum of 20 representative patients per exam. (Representative patients are defined as those within the weight range 60 – 80 kg (mean 70 kg)). In combination, these assessments will identify if doses are consistently exceeding prescribed levels. They will also assist in monitoring of the effectiveness of any actions which may have been deemed necessary to reduce patient doses.

Results of equipment testing are also included in the overall dose monitoring protocol.

It is also important to monitor the radiation doses that are delivered to paediatric patients. National DRLs are available for only a limited range of paediatric examinations, and these are split into doses for specific age ranges. The regional patient profile for PTHB does not allow rigorous comparisons to these doses for many examinations. It is usually necessary to review data for blocks of approximately 3 years. Paediatric doses will be monitored, by means of data recorded in RADIS and/or DMS.

3.2 Procedure for DRL Review

PTHB will undertake regular reviews and whenever DRLs are consistently exceeded and ensure that corrective action is taken where appropriate. Consideration will also be given to the appropriateness of the LDRL.

Each Area will carry out an annual review of the local DRLs as described in IPEM (2004). This will consist of a minimum of the following questions, together with any action plans that arise in the questioning.

Is this set of local DRLs still representative of the clinical workload?
Has any of the equipment or practices changed since the last review? Is the current list still adequate to represent all equipment?
Has any dose audit caused consideration to be given to changing a local DRL? Have new national recommendations on DRLs been made?

It is the responsibility of the nominated DRL leads to initiate the review. This review will be carried out by a reviewing team which should consist of a minimum of the nominated DRL leads and the MPE. The review will be reported to the RPC.

Both data collection pathways will be used to highlight trends in dose levels as well as showing installations which lie outside of the normal range within the organisation and nationally.

Data collected during audit will initially be considered to have exceeded the local DRL if the mean of the collected doses (or other indicator) exceeds the local DRL by more than 20%. In such cases a second indicator of compliance will be used based on the standard error on the mean (SEM). If the audit mean dose exceeds the local DRL by more than twice the SEM, there can be a high level of confidence that the local DRL has been exceeded. If a data set is found to have exceeded the local DRL an action plan will be devised by the reviewing team this will include timescales for actions.

Following the installation of new equipment, a dose audit should be instigated by the appropriate DRL lead once the exposure parameters have been finalised. This audit data should be available for the annual review if at all possible.

4. References

SI (). The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.

ARSAC (2018). Notes for Good Guidance on Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources.

IPEM (2004). Guidance on the Establishment and use of Diagnostic Reference.

Levels for Medical X-Ray Examinations, Institute of Physics & Engineering in Medicine, Report 88. York: IPEM.

STANDARD OPERATING PROCEDURE J

Significant Accidental or Unintended Exposures (SAUE) IR(ME)R Schedule 2(1) (k & L) - PROCEDURE TO MINIMISE ACCIDENTAL OR UNINTENDED RADIATION EXPOSURES OF PATIENTS (including clinically significant exposures)

Contents

- 1. Introduction and Purpose**
- 2. Scope**
- 3. Accidental and Unintended Radiation Exposure to Patients**
- 4. Incident Reporting**
- 5. References**

Appendix 1 – Radiation incident reporting flowchart

1. Introduction and Purpose

PTHB is committed to providing and maintaining a safe working environment for all its employees, patients and any other persons who may be affected by its activities involving ionising radiation.

This procedure addresses the issues concerning patients exposed to ionising radiation from diagnostic radiological procedures; and is intended to conform with the requirements of Regulation 8 schedule 2(1)(K & L) Ionising Radiation (Medical Exposure) Regulations (SI 1322).

The purpose of this procedure is to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

2. Scope

This procedure applies to all Radiology, dental staff and those using the Mini C-arm, involved in the exposure of patients for diagnostic.

3. Accidental and Unintended Radiation Exposure to Patients

Accidental exposure- an individual has received an exposure in error, when no exposure of any kind was intended.

Unintended exposure; although an exposure of an individual was intended the exposure they received was significantly greater or different to that intended. E.g. the dose received, technique carried out. These can happen for many reasons including procedural, systematic or human error. They can also occur due to malfunction of X-ray equipment or ancillary equipment.

3.1 Unintended exposure due to Operator Error (X-ray procedures)

To reduce the likelihood of an Operator error, all staff undergo appropriate in-house training on the operation of equipment and care is taken at all times whilst examining patients, to select and operate equipment correctly.

Unintended exposure can also occur due to human error, particularly in areas without anatomically programmed generators. In these rooms, operators are manually setting exposure factors and errors may occur i.e. 32 mAs instead of 3.2 mAs may be set for a chest radiograph. It is essential that operators are made aware during their training that this is a possible cause of unintended exposure and that such an error would require investigation.

If, having carried out an exposure, the operator knows or believes that the dose imparted was greater than intended, they must immediately report the incident (see Incident Reporting below).

3.2 Unintended exposure due to Equipment (X-ray procedures)

To prevent unintended exposures due to equipment, all equipment is subject to regular preventative maintenance as advised by the manufacturer. Also the department operates a Quality Control programme in line with the requirements of IPEM Report 91 (IPEM 2005). Equipment faults are logged in the equipment or room 'log book', and reported to the Superintendent radiographer /dental for the particular equipment. Equipment that is exhibiting faults likely to cause excessive radiation dose to a patient should be taken out of use, until repaired by a competent service engineer.

The operator should be trained to recognise when an exposure is not terminating as planned and take action to terminate the exposure manually.

If it is suspected that a dose is significantly different from the exposure intended was the result of an equipment fault, priority should be given to removing the suspect equipment from clinical service. The operator should label the equipment as unfit for use, warn other staff working in the area, and report immediately to the RPS and Professional Head of service for the particular equipment and notify the RPA. The person receiving this report should ensure that the equipment is out of service and arrange for QA tests to be carried out to establish performance standards. If the performance is outside tolerance, that person should arrange for a service visit from the maintenance contract provider. Incident form will be completed as soon as possible (see Incident Reporting below).

3.3 Accidental / Unintended exposures due to failure to follow procedures

PTHB has procedures in place to ensure that:

- Each patient is correctly identified.
- That a pregnant abdomen is not unintentionally exposed to ionising radiation.
- That each exposure of ionising radiation is justified.

If these procedures are followed, then an inappropriate dose of ionising radiation to a patient should not occur.

In the unlikely event of this occurring, however, the Operator responsible should inform the Head of Service for the particular area of clinical practice and the Radiation Protection Supervisor who will investigate the exposure. See incident reporting below.

4. Incident Reporting

Refer to flowchart in Appendix 1.

If, having carried out an exposure, the operator knows or believes that the dose imparted was accidental or unintended, they must report the incident following the Health Board's Adverse Incident, Hazard and Near Miss reporting policy and procedures and complete a Radiation Incident Report

Fact Sheet (available from intranet or Medical Physics) as soon as possible. This should be sent to the relevant local contact as soon as possible and local investigation procedures followed. The operator should identify themselves, the individual exposed, the equipment used and the relevant exposure parameters. If the dose imparted is believed to be significantly different from that intended, this must clearly be indicated on the incident form.

The Radiation Protection Supervisor, Department senior staff (e.g. Superintendent Radiographer, Professional Head, Dental Lead) and RPA/MPE should be notified and the RPA/MPE will decide if the exposure is such that notification is required to the relevant external bodies. If the incident occurred as a result of Referrer, Practitioner, Operator or Equipment error or equipment fault, then Healthcare Inspectorate Wales (HIW) are the regulatory body that would be notified.

In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) may need to be informed under the Adverse Incident Reporting Scheme.

If it seems likely that an incident has occurred that needs to be externally reported, the Head of Service will provide initial notification in consultation with the PTHB executive and Corporate Concerns team. Radiology/Dental staff will carry out a detailed investigation in collaboration with the RPA/MPE and referring department and report findings via the Quality & Safety committee structure.

Refer to SAUE criteria

https://www.cqc.org.uk/sites/default/files/20200826_saue_guidance_updated_aug20.pdf

If a clinically significant unintended or accidental exposure occurs the referrer, practitioner and the individual exposed (or their representative) are informed of the occurrence and of the outcome of the investigation of the incident.

Radiology/Dental will monitor incidents and provide a summary report including lessons learnt on all radiation incidents for the Radiation Protection Committee and Quality and Safety Committee.

Duty of Candour: Radiology recommend that the patient or their representative is informed of accidental or unintended exposures whether clinically significant or not.

The regulation allows for circumstances where it is not in the best interests of the patient to be informed of such an exposure. Such circumstances will be exceptional and in practice the practitioner and the referrer should be involved in this decision and the basis for the decision recorded in the patient's notes. In such cases however, it is recommended that a representative of the patient is informed wherever possible

5. References

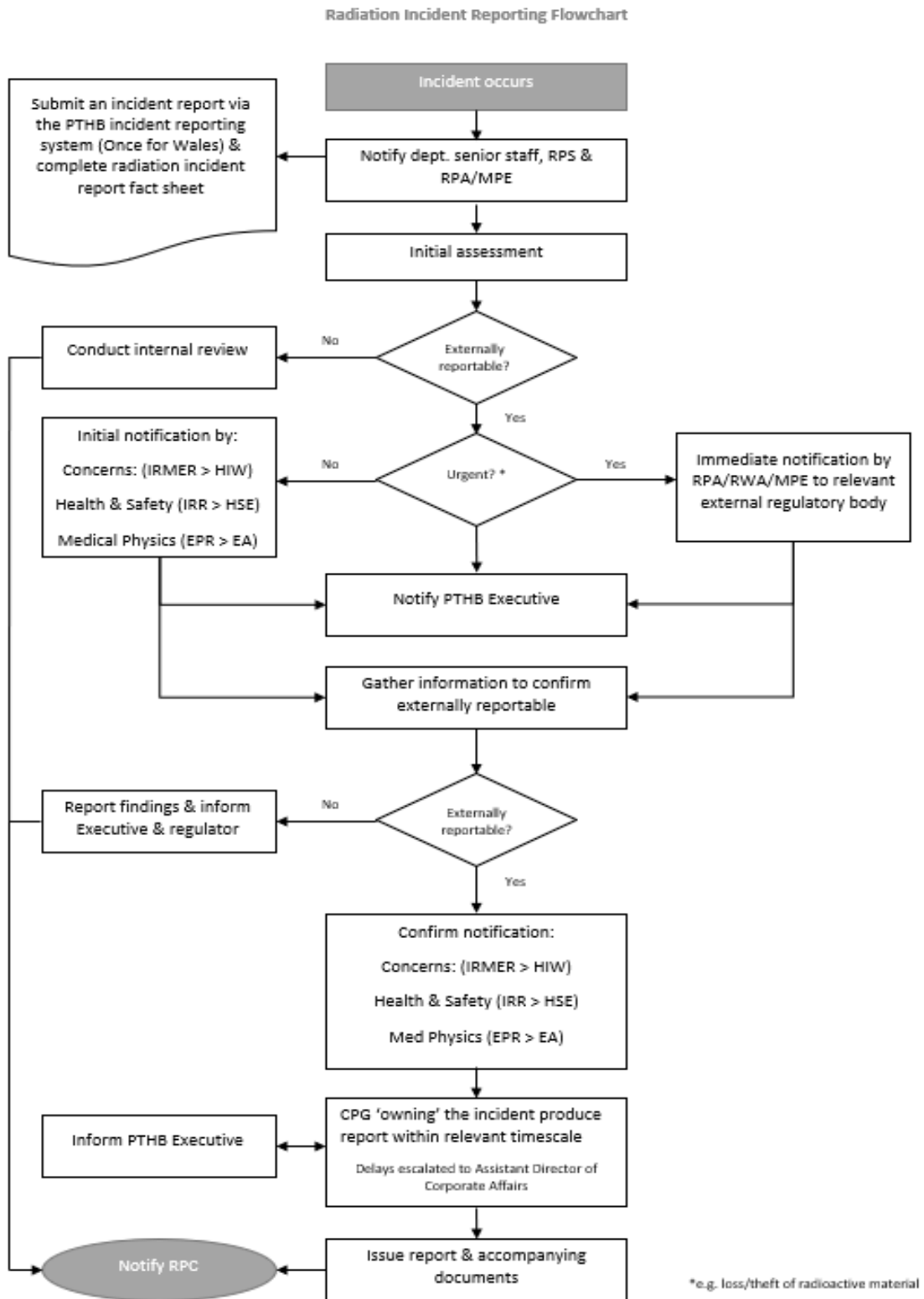
IPEM (2005). Recommended standards for the routine performance testing of diagnostic x-ray imaging systems. Institute of Physics and Engineering in Medicine Report 91. York: IPEM.

SI (). Ionising Radiation (Medical Exposure) Regulations Statutory Instrument No 1322. London: HMSO

SI (2006) Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 Statutory Instrument 2006 No 2523. London: HMSO

CQC (June 2019) Significant Accidental and Unintended exposures under IR(ME)R – Guidance for employers and duty-holders.

Appendix 1 Radiation Incident Reporting Flowchart



STANDARD OPERATING PROCEDURE K

RESEARCH EXPOSURE

Scope: All staff involved in research.

Purpose / Objective

All researchers wishing to incorporate medical exposures in their studies need to contact the Health Boards Research and Development Committee.

In all instances, ultimate approval for the project as a whole will lie with IRAS, which will ensure that the applicant holds all the necessary authorisations. No person will carry out a medical exposure for the purpose of research unless it has been approved by IRAS.

No Direct Medical Benefit to Individuals Undergoing Exposure

Where there is no direct medical benefit to individuals undergoing an exposure as part of a research project a dose constraint will be applied based on the risk to the individual and the benefit to society required to justify the exposure.

Level of risk to individual	Dose constraint (mSv)	Benefit to Society
Trivial	< 0.1	Minor
Minor	0.1 – 1	Intermediate
Intermediate	1 – 10	Moderate
Moderate	>10	Substantial

All dose constraints are set out in the Ethical Application of the research and this document must be made available for reference prior to commencing the research activity and exposing the patient.

The submission to IRAS should specify the appropriate dose constraint and the Practitioner will ensure that the total dose from all diagnostic procedures associated with the protocol does not exceed the dose constraint.

Where there is a diagnostic or therapeutic benefit the above dose constraints are not appropriate but the MPE will set an individual target level of dose.

The Practitioner will satisfy himself that the individuals concerned participate voluntarily in the research programme and ensure that they have been informed in advance about the risks of exposure.

Where necessary prior advice will be obtained from the Medical Physics expert.

**STANDARD OPERATING PROCEDURE L: NECESSARY RADIATION
EQUIPMENT / STANDARD OPERATING PROCEDURE M: QUALITY
ASSURANCE**

**IR(ME)R [SI] Schedule 2(1)(d) - Procedure for Quality Assurance of IR(ME)R
Procedures and Equipment**

Contents

- 1. Purpose**
- 2. Scope**
- 3. IR(ME)R Documents QA**
 - 3.1 Auditing of IR(ME)R procedures
 - 3.2 Imaging protocols
- 4. Equipment QA**
 - 4.1 General content of equipment QA procedure
- 5. Document Control**
- 6. References**

Appendix 3 – General Radiology Template

1. Purpose

The purpose of this procedure is to ensure that all procedures and protocols related to IR(ME)R are subject to a Quality Assurance Programme. Also, that all equipment covered by IR(ME)R is subject to a Quality Assurance Programme.

2. Scope

This procedure applies to all radiology and dental staff, and those using the Mini C-arm Image Intensifier and relates to IR(ME)R [SI] Schedule 2(1)(d).

3. IR(ME)R Documents QA

It is the responsibility of the Superintendent radiographer, or head of dental services, to regularly review IR(ME)R documents. The reviews will take place as part of the cycle of business of the Radiation Protection Committee. (Medical Physics Experts from the supporting Health Boards attend this meeting). All IR(ME)R documents will be reviewed every two years.

In addition, a review will also take place as necessary following, for example; new national guidance, radiation incidents, changes in equipment or new techniques.

Following the review, the procedure, along with any amendments, will be submitted to the Radiation Protection Committee for final approval. Following approval, the reviewed version will replace the existing version on the intranet.

Following changes in documentation, it is a requirement for previous policies and procedure to be kept as a permanent record for reference and risk management purposes. The legacy version will be filed.

Assurance of reviews being undertaken will be provided by the heads of radiology and dental services and manager with responsibility for the Mini C-arm to the Radiation Protection Committee.

3.1 Auditing of IR(ME)R Procedures

Radiology, Community Dental Services and theatres where the mini C-arm is used will ensure auditing of the IR(ME)R procedures is part of the annual audit programme, which will include as a minimum the following:

- Patient Identification
- Checking Pregnancy Status
- Recording of Dose
- Recording of Justification and Authorisation
- Incidents and 'Near Misses'

3.2 Imaging Protocols

It is the responsibility of the dental service head and the Superintendent Radiographers with their supporting HB to review their imaging technique

protocols every two years (as a minimum) on a routine basis, but also as necessary following new guidelines, incidents, changes to equipment and techniques etc.

Technique protocols should be re-dated and amended as appropriate.

Records of technique protocols prior to any changes must be kept for information/risk management purposes.

The signature of the radiographer reviewing the protocol must be recorded along with the date.

Changes to technique protocols must be agreed through the approved approvals process for radiology written controlled documents.

4. Equipment QA

It is the responsibility of the Superintendent Radiographer, Head of Dental services and manager responsible for Mini C-arm and appropriate Image Optimisation Team (IOT) to ensure that a quality assurance programme for all imaging equipment is in place and regularly reviewed. An appropriate Medical Physics Expert (MPE) will be involved in this process.

In addition, a review of the equipment QA programme will also take place as necessary following, for example; new national guidance, radiation incidents, changes in equipment or new techniques. For assurance purposes a compliance report of the Equipment QA will be provided to the Radiation Protection Committee Annually

4.1 General Content of Equipment QA Procedure

The testing programme for equipment to be used for medical radiological purposes must include the tests require for acceptance testing of new equipment, routine performance QA and following any major change which could affect the performance and/or patient dose, such as X-ray tube replacement.

QA testing should also be performed following routine servicing of the equipment.

General guidance on equipment QA is given in IPEM 2005 and BIR 2001.

Each QA procedure should include:

- An outline of the tests to be performed
- The frequency of testing
- Define how results are to be recorded and reviewed
- Specified acceptable performance criteria and when corrective action may be required (e.g. define remedial and suspension levels).
- Identify those responsible for: ensuring testing done; performing tests; reviewing and responding to results

5. Document Control

All documents must contain:

- Author
- Date Activated
- Date Approved
- Date to be reviewed
- Approving body
- Document Reference Number
- Number of Pages
- Version Number

6. References

BIR 2001. Assurance of quality in the diagnostic imaging department, 2nd edition. British Institute of Radiology. London: BIR.

IPEM 2002. Medical and Dental Guidance Notes. Institute of Physics and Engineering in Medicine. York: IPEM.

IPEM 2005. Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems, Institute of Physics and Engineering in Medicine Report 91. York: IPEM.

SI . The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO.

STANDARD OPERATING PROCEDURE N

Quality Assurance procedures to ensure that the probability and magnitude of accidental or unintended doses to patients, from radiological practices, are reduced so far as reasonably practicable

IR(ME)R Schedule 2(1) (k & L) - PROCEDURE TO MINIMISE ACCIDENTAL OR UNINTENDED RADIATION EXPOSURES OF PATIENTS (including clinically significant exposures)

Contents

6. Introduction and Purpose

7. Scope

8. Accidental and Unintended Radiation Exposure to Patients

9. Incident Reporting

10. References

Appendix 1 – Radiation incident reporting flowchart

6. Introduction and Purpose

PTHB is committed to providing and maintaining a safe working environment for all its employees, patients and any other persons who may be affected by its activities involving ionising radiation.

This procedure addresses the issues concerning patients exposed to ionising radiation from diagnostic radiological procedures; and is intended to conform with the requirements of Regulation 8 schedule 2(1)(K & L) Ionising Radiation (Medical Exposure) Regulations (SI 1322).

The purpose of this procedure is to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

7. Scope

This procedure applies to all Radiology, dental staff and those using the Mini C-arm, involved in the exposure of patients for diagnostic.

8. Accidental and Unintended Radiation Exposure to Patients

Accidental exposure- an individual has received an exposure in error, when no exposure of any kind was intended.

Unintended exposure; although an exposure of an individual was intended the exposure they received was significantly greater or different to that intended. E.g. the dose received, technique carried out. These can happen for many reasons including procedural, systematic or human error. They can also occur due to malfunction of X-ray equipment or ancillary equipment.

8.1 Overexposures due to Operator Error (X-ray procedures)

To reduce the likelihood of an Operator error, all staff undergo appropriate in-house training on the operation of equipment and care is taken at all times whilst examining patients, to select and operate equipment correctly.

In particular, the operator should be trained to recognise when an exposure is not terminating as planned and take action to terminate the exposure manually.

Overexposures can also occur due to human error, particularly in areas without anatomically programmed generators. In these rooms, operators are manually setting exposures factors and errors may occur i.e. 32 mAs instead of 3.2 mAs may be set for a chest radiograph. It is essential that operators are made aware during their training that this is a possible cause of overexposure and that such an error would require investigation.

If, having carried out an exposure, the operator knows or believes that the dose imparted was greater than intended, they must immediately report the incident (see Incident Reporting below).

8.2 Overexposures due to Equipment (X-ray procedures)

To prevent overexposures due to equipment, all equipment is subject to regular preventative maintenance as advised by the manufacturer. Also the department operates a Quality Control programme in line with the requirements of IPEM Report 91 (IPEM 2005). Equipment faults are logged in the equipment or room 'log book', and reported to the Superintendent radiographer /dental for the particular equipment. Equipment that is exhibiting faults likely to cause radiation dose overexposure of a patient should be taken out of use, until repaired by a competent service engineer.

If it is suspected that a dose is significantly different from the exposure intended was the result of an equipment fault, priority should be given to removing the suspect equipment from clinical service. The operator should label the equipment as unfit for use, warn other staff working in the area, and report immediately to the RPS and Professional Head of service for the particular equipment and notify the RPA. The person receiving this report should ensure that the equipment is out of service and arrange for QA tests to be carried out to establish performance standards. If the performance is outside tolerance, that person should arrange for a service visit from the maintenance contract provider. Incident form will be completed as soon as possible (see Incident Reporting below).

8.3 Overexposures due to failure to follow procedures

PTHB has procedures in place to ensure that:

- Each patient is correctly identified.
- That a pregnant abdomen is not unintentionally exposed to ionising radiation.
- That each exposure of ionising radiation is justified.

If these procedures are followed, then an inappropriate dose of ionising radiation to a patient should not occur.

In the unlikely event of this occurring, however, the Operator responsible should inform the Head of Service for the particular area of clinical practise and the Radiation Protection Supervisor who will investigate the exposure. See incident reporting below.

9. Incident Reporting

Refer to flowchart in Appendix 1.

If, having carried out an exposure, the operator knows or believes that the dose imparted was accidental or unintended, they must report the incident following the Health Board's Adverse Incident, Hazard and Near Miss

reporting policy and procedures and complete a Radiation Incident Report Fact Sheet (available from intranet or Medical Physics) as soon as possible. This should be sent to the relevant local contact as soon as possible and local investigation procedures followed. The operator should identify themselves, the individual exposed, the equipment used and the relevant exposure parameters. If the dose imparted is believed to be significantly different from that intended, this must clearly be indicated on the incident form.

The Radiation Protection Supervisor, Department senior staff (e.g. Superintendent Radiographer, Professional Head, Dental Lead) and RPA/MPE should be notified and the RPA/MPE will decide if the exposure is such that notification is required to the relevant external bodies. If the incident occurred as a result of Referrer, Practitioner, Operator or Equipment error or equipment fault, then Healthcare Inspectorate Wales (HIW) are the regulatory body that would be notified.

In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) may need to be informed under the Adverse Incident Reporting Scheme.

If it seems likely that an incident has occurred that needs to be externally reported, the Head of Service will provide initial notification in consultation with the PTHB executive and Corporate Concerns team. Radiology/Dental staff will carry out a detailed investigation in collaboration with the RPA/MPE and referring department and report findings via the Quality & Safety committee structure.

If a clinically significant unintended or accidental exposure occurs the referrer, practitioner and the individual exposed (or their representative) are informed of the occurrence and of the outcome of the investigation of the incident.

Radiology/Dental will monitor incidents and provide a summary report including lessons learnt on all radiation incidents for the Radiation Protection Committee and Quality and Safety Committee.

Duty of Candour: Radiology recommend that the patient or their representative is informed of accidental or unintended exposures whether clinically significant or not.

The regulation allows for circumstances where it is not in the best interests of the patient to be informed of such an exposure. Such circumstances will be exceptional and in practice the practitioner and the referrer should be involved in this decision and the basis for the decision recorded in the patient's notes. In such cases however, it is recommended that a representative of the patient is informed wherever possible

10. References

IPEM (2005). Recommended standards for the routine performance testing of diagnostic x-ray imaging systems. Institute of Physics and Engineering in Medicine Report 91. York: IPEM.

SI (). Ionising Radiation (Medical Exposure) Regulations Statutory Instrument No 1322. London: HMSO

SI (2006) Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 Statutory Instrument 2006 No 2523. London: HMSO

CQC (June 2019) Significant Accidental and Unintended exposures under IR(ME)R – Guidance for employers and duty-holders.

STANDARD OPERATING PROCEDURE O

Procedure for Dealing with Carers and Comforters within Radiology

Contents

- 1. Introduction and Purpose**
- 2. Background and Scope**
- 3. Definitions**
 - 3.1 Carer and Comforter
 - 3.2 Dose Constraint
- 4. Justification**
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 - 5.1 X-ray procedures
 - 5.2 Practitioner for General X-ray (incl. Dental), fluoroscopy
- 6. Enforcement**
- 7. Enquiries**
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1. Introduction and Purpose

The purpose of this procedure is to provide guidance for the exposure of carers and comforters and define suitable dose constraints. The procedure defines comforters and carers and what to do if they are involved in a medical exposure of another person within Radiology.

This procedure is written to comply with Regulation 6 and Schedule 2(1)(n) of the Ionising Radiation (Medical Exposure) Regulations [SI b]. It is the responsibility of PTHB to ensure this procedure is in place and to ensure compliance by practitioners and operators.

2. Background and Scope

This procedure is related to all diagnostic exposures undertaken by Radiology and includes all radiological investigations involving ionising radiation. National guidance has been used in formulating this procedure (see references).

Whenever practicable, those generally considered 'Carers and Comforters within the health service will not be present during the radiological exposure.

3. Definitions

3.1 Carers and Comforters

According to IR(ME)R , these are "... individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure." [SI b] i.e. relatives and friends.

Therefore, only relatives or friends of a patient participating 'knowingly and willingly' are strictly 'carers and comforters' under this definition.

Other persons (not employees) who may be subject to an exposure e.g. due to contact with a patient administered with a radioactive material, are to be treated as members of the public and subject to the dose limits in the Ionising Radiations Regulations [SI a]. Similarly, employees required to support patients as part of their occupation, are not carers/comforters but must be subject to the dose limits in the Ionising Radiations Regulations [SI a].

3.2 Dose Constraint

According to IR(ME)R a "dose constraint means a restriction set on the prospective doses of individuals which may result from a given radiation source" [SI b].

Such dose constraints must be established for carers and comforters, which should be set locally by the employer for the location where the exposure

takes place. A dose constraint of 5 mSv can be considered appropriate for most circumstances [DH 2018].

For X-ray procedures and diagnostic nuclear medicine procedures, a dose constraint of 1 mSv will be applied.

4. Justification

According to IR(ME)R a “A person must not carry out an exposure unless it has been justified by the practitioner as showing a sufficient net benefit. The following must be considered when justifying an exposure, IR(ME)R Reg. 11(2).

- The specific objectives of the exposure and the characteristics of the individual involved
- The total potential diagnostic or therapeutic benefits to the individual and society from the exposure
- The detriment the exposure may cause
- What alternative imaging modalities are available that could answer the diagnostic question but involve less or no radiation?

According to IR(ME)R Reg. 11(3)(b), there are some additional considerations when justifying an exposure to a carer or comforter (Requirement Hints [RCR 2020 Table 16.3]):

- Any likely health benefits to the patient being examined.
- Possibility of having a diagnosis or treatment or knowing there is no underlying medical issue.
- Any possible benefits to the carer or comforter.
- Knowledge that a family member, partner, friend or dependent is receiving medical attention and will be able to have the examination, with their support.
- The detriment the exposure may cause.
- What is the likely dose to the carer or comforter from the exposure?
- What is the risk to the individual from that dose?

5. Process

- The IR(ME)R Operator performing the exposure is responsible for deciding if a carer/comforter is required to assist or support a patient.
- In order to minimise the radiation exposure, a single carer/comforter should be selected wherever possible.
- The IR(ME)R Operator entitled to act as a practitioner for carers and comforters (see below), must justify the potential exposure of the carer/comforter, taking into account the benefits and risks. These must be explained to the person and they must knowingly and willingly participate.
- Individuals who are pregnant would not normally be designated as carers and comforters. It is preferable for a non-pregnant relative or friend to offer support instead, but this may not always be practicable.
- Likewise, individuals under 18 years of age who act in a caring role would not normally be designated as carers and comforters. The Health Board

procedure for consent should be followed to determine whether a person under 18 years can 'knowingly and willingly' consent to an exposure as a carer and comforter.

- It has been shown that good radiation protection practice has a significant role in achieving dose reduction when support is provided to the patient. Hence the quality of information/instruction provided to the supporter and how clearly the relevant advice is provided may have a more significant impact on exposure than patient dose reduction alone [HSE 2003].
- A risk assessment into the likely doses for carers/comforters is available.

5.1 X-ray procedures.

- Carers and comforters will only exceptionally be required to physically participate in an exposure of a patient.
- The Operator will provide clear instructions to the supporter on where they should be positioned and what they are required to do. This should include information on how they will know when an exposure is taking place and any warnings required.
- The Operator will position the carer/comforter and select exposure parameters to keep their dose as low as reasonably practicable (ALARP)
- Appropriate personal protective equipment (PPE) must be provided.
- Dose monitoring will be performed by requiring the carer/comforter to wear the department holding badge outside the apron on the shoulder closest to the patient. An entry for the person acting as a carer/comforter will be made in the holding badge record log. In circumstances when more than one carer/comforter may be required, then the one likely to receive the highest radiation dose should be supplied with the badge.
- The results will be regularly reviewed to ensure they do not exceed a dose constraint of 1 mSv for all X-ray procedures [HSE 2003]
- If the dose constraint is exceeded the Radiology Service Manager must undertake an investigation and record on Datix.

5.2 Practitioner for General X-ray (incl. Dental), fluoroscopy

Radiographers will be entitled to act as practitioners for carers and comforters. As part of the entitlement process all practitioners will have received training in radiation safety of carers and comforters. The individual's entitlement will be included on the IR(ME)R entitlement matrix.

6. Enforcement

Breaches in procedure should be reported to the Head of Radiography.

Failure to comply with this procedure could lead to investigation by the Health Board, which may result in disciplinary action being taken.

7. Enquiries

Any enquiries regarding the operation of this procedure should be made to the Head of Radiography.

8. References

- DH 2018. Guidance to the Ionising Radiation (Medical Exposure) Regulations . Department of Health and Social Care (June 2018).
<https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations--guidance>
- HSE 2003. Dose constraints for comforters and carers. Health and Safety Executive Research Report 155.
<http://www.hse.gov.uk/research/rrpdf/rr155.pdf>
- HSE . Work with ionising radiation, Health & Safety Executive, Approved Code of Practice and Guidance L121, 2nd edition. London: HMSO.
<http://www.hse.gov.uk/pubns/books/l121.htm>
- IPEM 2002 Medical and Dental Guidance Notes
- RCR 2020. IR(ME)R. Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine. Joint Working Party report. Royal College of Radiologists BFCR(20)3. Available here:
<https://www.rcr.ac.uk/publication/irmer-implications-diagnostic-imaging-interventional-radiology-diagnostic-nuclear-medicine>
- SI a. The Ionising Radiations Regulations . Statutory Instrument No 1075. London: HMSO. <http://www.legislation.gov.uk/uksi//1075/contents/made>
- SI b. The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO
<http://www.legislation.gov.uk/uksi//1322/contents/made>

STANDARD OPERATING PROCEDURE P

Communicating the benefits and risks of ionising radiation prior to an examination as required by IR(ME)R 17

Any enquiries regarding the operation of this procedure should be made to the Radiography staff within the department responsible for making the exposure.

Contents

- 1. Introduction and Purpose**
- 2. Background and Scope**
- 3. Roles and responsibilities**
 - 3.1 Referrer -- (Medical and Non-Medical referrers)
 - 3.2 Practitioner
 - 3.3 Operator
 - 3.4 Department exposing patient
- 4. Staff training**
- 5. Communicating Benefits and Risks**
 - 5.1 Posters
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 - 5.4.2 Non-medical imaging using imaging equipment
 - 5.5 Imaging modality specific information
 - 5.6 Consent Process
 - 5.7 Record keeping
- 6. Risk categories**
- 7. References**

Appendix 1 – Radiation Dose and Risk Guide – Female.

Appendix 2 – Radiation Dose and Risk Guide – Male.

Appendix 3 – Risk Guide Discussion.

1. Introduction and Purpose

The purpose of this procedure is to provide guidance on giving information on the benefits and risks of associated with the radiation dose from an exposure.

This procedure is written to comply with Regulation 6 and Schedule 2(1)(i) of IR(ME)R, the Ionising Radiation (Medical Exposure) Regulations [SI]. It is the responsibility of NHS Wales organisations using ionising radiation to ensure this procedure is in place and to ensure compliance by all IR(ME)R referrers, practitioners & operators. This includes providing adequate training for IR(ME)R duty holders (Schedule 3) on the benefits and risks of radiation and risk communication.

2. Background and Scope

This procedure is relevant for all diagnostic investigations involving ionising radiation, undertaken within PTHB. This includes not only radiology but also,, orthopaedic clinicians using a mini c-arm fluoroscopy unit.

National guidance has been used in formulating this procedure (see references).

3. Roles and responsibilities

The discussion on benefit and risk of radiation is a shared responsibility between the IR(ME)R duty holders: Referrer, Practitioner and Operator.

3.1 Referrer -- (Medical and Non-Medical referrers)

The referrer is defined as a registered healthcare professional who is entitled (by the organisation undertaking the exposure) to refer individuals for an exposure to an IR(ME)R practitioner. For NHS Wales this includes medical and non-medical Referrers.

All referrers must be aware of the risks of the radiation dose for the examinations that they refer for. This information can be found in i-refer <https://www.irefer.org.uk/guidelines>. Additional information on radiation dose and risk is provided at the end of this document.

A reminder of the risk categories will be sent annually to referrers by Radiology as part of the annual IR(ME)R entitlement reminder.

The referrer when referring a patient for an examination involving ionising radiation must include in the conversation with the patient a discussion of the benefits and risk of the radiation as part of the patients care pathway. This forms part of the consent process for the examination.

3.2 Practitioner

The Practitioner under IR(ME)R is a suitably trained and entitled individual usually a radiologist or a radiographer but in some circumstances may be a cardiologist, vascular surgeon or orthopaedic surgeon (when using the mini c-arm).

The practitioner is required to justify the exposure as showing a sufficient net benefit compared with the risks.

If the practitioner amends the referral they need to inform the referrer of the change.

When the practitioner is involved in performing the examination directly with the patient they have a responsibility to discuss the benefits and risks prior to the exposure where practicable.

Where the practitioner is not involved directly with the patient they have a responsibility for supporting the development of appropriate information for referrers and operators of the benefits and risks. This is particularly important in the development of appropriate pathways including 'direct to test'.

3.3 Operator

IR(ME)R defines the operator as any person entitled to carry out the practical aspects of the exposure e.g. includes identification, establishment of pregnancy status, making the exposure.

All operators who initiate an exposure or administer a radioactive substance must ensure they understand the benefit and risks of the exposure they are to perform. Where they do not have the required information to be able to answer the patient's or their representative's questions they must seek support from a more experience operator or a practitioner as appropriate.

3.4 Department exposing patient

The employer's procedure should specify how benefit and risk information is delivered, to ensure a consistent message is provided across the patient pathway.

Each department using ionising radiation will ensure that operators and practitioners are appropriately trained to understand the radiation risks and benefits to the patient's pathway for the examinations that they have entitlement. All practitioners and operators must have access to the risk categories information below to support discussions with patients.

Each department will ensure that posters and written information referred to in this document are used.

4. Staff training

Schedule 3 includes the requirement for IR(ME)R duty holders to have adequate training on the benefits and risks of radiation and risk communication.

For verbal discussions, national guidance [RCR 2020] suggests some things to consider:

- Provide adequate information to support the individual being exposed to make an informed decision about the examination they are being offered.
- Importance of ensuring the benefits of the exposure are clearly described along with the implications of not having the examination.
- It may be appropriate to describe the system of justification and optimisation and overall governance arrangements to enhance patient confidence. Doing the right procedure (justification) and Doing the right procedure right (optimisation)
- Awareness of difficulties for patients processing information at the time of the consultation or examination and the wide variation in the perception of risk and radiation amongst individuals
- Use of standard phrases to ensure consistent message.
- Patient dignity, when choosing the location for discussion
- Sufficient time for questions
- Availability of additional advice

5. Communicating Benefits and Risks

Regulation 6 Schedule 2 (i) States that patients or their representative should be given information on the benefit and risk prior to the exposure as far as reasonably practicable.

The minimum information provided will be in the form of posters in the department and a standard statement included in patient information letters and leaflets. These can be supplemented with verbal discussion with the patient or representative, as required.

The complexity of the examination and level of risk will also affect the method(s) of communication.

PTHB will ensure that referrers, operators and practitioners receive training in radiation protection. Audit of compliance with this procedure will be undertaken as part of the IR(ME)R audit programme.

5.1 Posters

The posters displayed in each imaging modality using ionising radiation will be those approved by the All Wales Imaging Quality Forum and the Radiation Protection Standing Specialist Advisory Group RPSSAG.

5.2 Appointment letters and information leaflets

Written information to patients should be amended to include the following statement: "The main benefit of the test is making the correct diagnosis, so you can get the treatment that's right for you. This benefit is far greater than the small risk from radiation."

5.3 When communication is not practicable

PTHB considers the following situations where it is not practical to provide information:

- Emergency life threatening situations, particularly where the patient is unconscious.
- Patients anaesthetised in theatre where it becomes necessary to perform unplanned imaging e.g. missing swabs.
- Sedated or unconscious patients from ITU, HDU or the emergency department.

5.4 Special procedures

5.4.1 Suspected Inflicted Injury (Non Accidental Injury) – Part of the consent process performed prior to the examination will include a discussion on the benefit and risks as directed in the guidance document "The Radiological investigation of suspected physical abuse in children" [RCR,].

5.4.2 Non-medical imaging using imaging equipment – Information leaflets specific to these examinations will be developed by departments where these examinations are performed.

5.5 Imaging modality specific information

Since different modalities may require different types of information concerning benefits and risks, departments should develop information leaflets for specific modalities.

Departments need to consider how to manage dissemination of these leaflets (for example, in the case of an inpatient) and define whose responsibility it is.

5.6 Consent Process

Benefit / risk discussions may be included in the consent process for the examination (e.g. theatres). It may also be particularly relevant for complex or high dose examinations (e.g. interventional/cardiology).

5.7 Record keeping

The employer's procedure should be clear as to when to keep a record of any additional information delivered and where this is recorded.

6. Risk categories

The use of quick reference radiation risk guides (see Appendix) may help explain to the individual the level of cancer induction risk associated with the examination. The simple descriptive phrases provided may help in communicating this information.

7. References

DH 2018. Guidance to the Ionising Radiation (Medical Exposure) Regulations . Department of Health and Social Care (June 2018).

<https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations--guidance>.

HSE 2003. Dose constraints for comforters and carers. Health and Safety Executive Research Report 155.

<http://www.hse.gov.uk/research/rrpdf/rr155.pdf>.

HSE . Work with ionising radiation, Health & Safety Executive, Approved Code of Practice and Guidance L121, 2nd edition. London: HMSO.

<http://www.hse.gov.uk/pubns/books/l121.htm>.

IPEM 2002 Medical and Dental Guidance Notes.

RCR 17. The Radiological investigation of suspected physical abuse in children. London: RCR.

RCR 2020. IR(ME)R. Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine. Joint Working Party report. Royal College of Radiologists BFCR(20)3. Available here:

<https://www.rcr.ac.uk/publication/irmer-implications-diagnostic-imaging-interventional-radiology-diagnostic-nuclear-medicine>

SI . The Ionising Radiation (Medical Exposure) Regulations . Statutory Instrument No 1322. London: HMSO

<http://www.legislation.gov.uk/ukxi//1322/contents/made>

WHO 2016 Communicating Radiation Risks in Paediatric Imaging

<http://www.who.int/phe>

Appendix 1 – Radiation Dose and Risk Guide (Female)

The following table has been produced for broad ranges of age and dose and is intended for illustrative purposes only. For information on specific situations please contact Medical Physics. The risk is based on the lifetime cancer induction risk.

Table 1 – Female Lifetime Cancer Induction Risk

Age at exposure	Dose range (mSv)				
	<0.1	0.1 to 1.0	1.0 to 10	10 to 20	20 to 100
Child					
Adult					
Adult ≥70 years					

Key to risk category: (quoted as 1 in ...)

	Negligible (>120,000)		Minimal (120,00 to 20,000)		Very Low (20,000 to 2,000)		Low (2,000 to 200)		Moderate (<200)
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Table 2 – Example examinations per dose range

Imaging modality	Dose range (mSv)				
	<0.1	0.1 to 1.0	1.0 to 10	10 to 20	20 to 100
Radiography	Chest; limbs; shoulder; teeth	Head; neck; spine; abdomen; pelvis; mammography	Multiple procedures		
Fluoroscopy			Contrast studies; angiography	Interventional radiology; angioplasty; EVAR	Multiple procedures
CT			Head; combinations of thorax, abdomen and pelvis	CT thorax abdomen and pelvis;	Multiple procedures and follow-up studies
Nuclear Medicine	SLNB breast (same day); GFR	Renogram; DMSA; Thyroid (Tc); SeHCAT; SLNB (next day)	Lung V/Q; Bone; Brain; HIDA; Cardiac (Tc); PET	In111-octreotide; I-123 thyroid mets; MPI(Tl201)	I131 thyroid mets

Appendix 2 – Radiation Dose and Risk Guide (Male)

The following table has been produced for broad ranges of age and dose and is intended for illustrative purposes only. For information on specific situations please contact Medical Physics.

Table 1 – Male Lifetime Cancer Incidence Risk

Age at exposure	Dose range (mSv)				
	<0.1	0.1 to 1.0	1.0 to 10	10 to 20	20 to 100
Child					
Adult					
Adult ≥70 years					

Key to risk category: (quoted as 1 in ...)

	Negligible (>120,000)		Minimal (120,000 to 20,000)		Very Low (20,00 to 2,000)		Low (2,000 to 200)		Moderate (<200)
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Table 2 – Example examinations per dose range

Imaging modality	Dose range (mSv)				
	<0.1	0.1 to 1.0	1.0 to 10	10 to 20	20 to 100
Radiography	Chest; limbs; shoulder; teeth	Head; neck; spine; abdomen; pelvis;	Multiple procedures		
Fluoroscopy			Contrast studies; angiography	Interventional radiology; angioplasty ; EVAR	Multiple procedures
CT			Head; combinations of thorax, abdomen and pelvis	CT thorax abdomen and pelvis;	Multiple procedures and follow-up studies