SOP33A-M: Standard Operating Procedure for Computerised Tomography in Clinical Imaging

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Approved by WWORTH JMG (Ian Russell in Chair)

Signature: [Signature]
Date: 26 October 2012

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**PLEASE PRINT THIS DOCUMENT IN COLOUR**
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2 Glossary


3 Introduction

Standard Operating Procedures (SOPs) are succinct formal documents designed to achieve consistency in specified trial functions by specifying standard practice in performing those functions (GCP 1.55 & 5.1.1 – EMeA, 2002). While SOPs should cite relevant legislation & regulations, and key references & evidence, they need not expound theory.

WWORTH SOPs should accord with all relevant regulations, including the European Union Clinical Trial Directive¹, ICH Good Clinical Practice (GCP)² and the current NHS Research Governance Framework³. They will seek to distinguish between regulations for Clinical Trials of a Medicinal Products (CTIMPs) and for other research.

This documents is a legal requirements to cover radiation exposure to adhere to Ionising Radiations Regulations 1999 Statutory Instrument 1999 No. 3232 (Ref 3) and Ionising Radiation (Medical Exposure) Regulations 2000 (Ref 4) together with Medical & Dental Guidance Notes- A Good Practice Guide to Implement Ionising Radiation Protection Legislation in the Clinical Environment. IPEM 2002. (Ref 5) The Health and Safety Executive is responsible for IRR99 and the Health Departments in England, Scotland and Wales are responsible for IR(ME)R2000.

Both IRR99 and IR(ME)R2000 apply to any employer who uses ionising radiation for medical purposes. This means any employer who undertakes medical exposures (e.g. diagnostic imaging, unsealed radioisotopes, nuclear medicine, radiotherapy etc). It also applies to employers whose employees carry out medical exposures, or provide health care for patients who have been administered radioactive medicinal products.

4 Purpose

The purpose of this SOP is to describe the process of radiation protection i.e. IR(ME)R 2000 together with IRR 99 and outline management responsibilities in relation to Radiation Protection.

The SOP will cover
A. Procedure for entitlement and identification of referrers, practitioners and operators for CT

B. Procedure for identification of individuals undergoing a CT medical exposure

C. Procedure for making enquires of females of childbearing age

D. Procedure for justification/authorisation of a CT medical exposure

E. Procedure for the clinical evaluation of a CT medical exposure

F. Procedure for the assessing of the patient radiation dose

G. Procedure for setting and monitoring diagnostic reference levels.

H. Procedure for accidental or unintended radiation exposure

I. Procedure for the exposure of individual participating in research studies

J. Procedure for document quality assurance.

K. Procedure for ensuring that the probability and magnitude of an accidental or unintended dose to the patient are reduced so far as is reasonably practicable

L. Procedure for the provision of imaging protocol and standard exposure factors.

This SOP will be followed by all staff involved in the use of CT equipment that initiates a radioactive exposure. All members of staff who use radiation, or are in any way involved with its use, shall do so only in accordance with the Local Rules (Appendix I). Staff who work with radiation shall exercise reasonable care, use any protective equipment provided, report any defect in such equipment, wear any radiation monitors provided and undertake any training deemed necessary.

5 Roles and Responsibilities

Chief Executives, Directors and line managers have clearly defined responsibility for Health and Safety under the Health and Safety at Work etc Act 1974 (HSW Act)(Ref 6). Both IRR99 and IR(ME)R2000 are enforced under
the HSW Act. Because employers have an important role under both sets of Regulations, awareness of responsibilities and accountability is needed.

Employers are obliged under the Management of Health and Safety at Work Regulations 1999 (MHSWR) (Ref 7) to assess workplace risks to employees and others who may be affected by the work in the organisation, in this case patients, their families and friends, and the general public.

This accountability under the HSW Act cannot be delegated to anyone else in the organisation. Although others may be employed to produce the policies and procedures which need to be implemented in the workplace, The Employer remains responsible in law for making sure these are in place.

If the safe use of ionising radiation in the workplace, is not managed effectively, then both the Health and Safety Executive and the Health Departments have a range of enforcement options available to them, depending on the seriousness of the offence. This range includes issuing enforcement notices and prosecution for breaches of the legislation. Prosecution can involve imprisonment and/or fines. Therefore a framework for radiation protection which effectively manages and controls the risk to both employees and patients must be in place.

Managers are responsible for ensuring that the necessary resources and facilities are available to ensure that staff can adhere to this policy. Managers are also responsible for ensuring that that staff are aware of the policy and work within its framework and that temporary staff are advised of any arrangements.

Employees are responsible for following the requirements of this policy and notifying managers of any areas of non compliance. All staff will work within the framework of the policy and report any concerns they have.

Ionising and non-ionising radiation shall be used only in accordance with current relevant legislation, approved codes of practice, guidance notes and other advisory documents. These shall be interpreted by Local Rules for CT and written by a designated Radiation Protection Adviser (RPA) in liaison with the appropriate Head of Department/College and the Radiation Protection Supervisor.

The designated responsibility for Health and Safety by the Executive Board is with the officer which overall responsibility including radiation safety and is committed to the principle of ensuring that exposures to ionising radiation are as low as reasonably practicable.
6 Procedure

6.1 SOP33A: Procedure for Entitlement and Identification of Referrers, Practitioners and Operators for CT

Purpose
IR(ME)R places specific responsibilities on duty holders (referrers, practitioners and operators) and demands standards of training for practitioners and operators. It is necessary for the College of Medicine to be able to identify responsible individuals and demonstrate that they are adequately trained.

Scope
Covers CT examinations performed using equipment that is the responsibility of the College of Medicine.

Responsibilities
The Head of the College of Medicine (HoC) will ensure that the structures described in this document for the entitlement of IR(ME)R duty holders are in place.

The HoC is responsible for entitling referrers to refer patients for CT examinations.

The HoC is responsible for entitling practitioners before they undertake this role for the first time.

The Clinical Lead is responsible for entitling operators before they undertake this role for the first time.

The Head of the ABMU LHB Radiation Protection Service will entitle suitably qualified and competent registered Clinical Scientists to undertake the role of Medical Physics Expert in diagnostic radiology. He will also entitle Radiation Protection Service staff to act as operators for specific tasks and ensure arrangements are in place to maintain up to date records of qualifications and training undertaken by each Medical Physics Expert or operator.

No individual may take on the role of referrer, operator or practitioner unless entitled to do so in accordance with this procedure.
Procedure

1. Referrers

Through approval of this procedure the HoC entitles all GMC registered medical doctors to refer individuals for CT examinations. No other training details are required. The HoC will ensure local arrangements are in place to verify that the referrer is medically qualified.

There are no non-medical referrers for CT examinations.

Referral Guidelines

Referral guidelines used by the College of Medicine for diagnostic radiology are: Making the Best Use of Clinical Radiology Services. Royal College of Radiologists. (Ref 8)

2. Practitioners

A practitioner is a registered healthcare professional who is entitled to take responsibility for an individual exposure. The primary function of the practitioner us to undertake the justification of medical exposure.

Through approval of this procedure the HoC entitles Consultant Radiologists, working within a Service Level Agreement or holding an honorary contract with the College of Medicine, to be practitioners for CT examinations.

3. Operators

An operator is any person who is entitled to carry out practical aspects of the procedure of the medical exposure. There may be several operators involved in a single exposure.

An entitlement matrix is maintained by the Clinical Lead, showing the scope of practice (operator tasks) for each entitled operator.

4. Practitioner and operator training records

The Clinical Lead shall make provisions to ensure that an up to date central record is kept of the scope of entitlement for each practitioner or operator supported by verifiable qualifications, training and experience.

Each duty holder will maintain a personal file that contains accurate details (nature and date) of education and training. The record should be compliant with any recommendations or mandatory requirements for Continuing Medical Education (CME) or
Continuing Professional Development (CPD).

Where the practitioner or operator is employed by another body, working within a Service Level Agreement or having an honorary contract with the College of Medicine, it is the responsibility of the other body to keep and maintain training records. The training records would compose of CVs, GMC, HPC registration number, GCP training and Honorary Contracts. These records will be made available to the College of Medicine on request.

### Table 1  Guidance on staff entitled to act as referrers, practitioners and operators

<table>
<thead>
<tr>
<th>Referrer</th>
<th>Expected level of Training</th>
<th>Scope of referral</th>
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<tbody>
<tr>
<td>Medical and Surgical Consultants</td>
<td>GMC registration and licence</td>
<td>Diagnostic CT examinations</td>
</tr>
<tr>
<td>Non-consultant Hospital Doctor</td>
<td></td>
<td></td>
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<tr>
<td>General Practitioners</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Practitioner</th>
<th>Expected level of Training</th>
<th>Scope of practice</th>
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<tr>
<td>Consultant Radiologists</td>
<td>FRCR</td>
<td>Diagnostic CT examinations</td>
</tr>
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<table>
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<tr>
<th>Operator Task</th>
<th>Employed as</th>
<th>Training requirements*</th>
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<tbody>
<tr>
<td>Performing CT radiography and</td>
<td>Diagnostic Radiographer</td>
<td>HPC registration + In-house competency</td>
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<tr>
<td>associated tasks excluding</td>
<td></td>
<td>training</td>
</tr>
<tr>
<td>clinical evaluation</td>
<td></td>
<td></td>
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<tr>
<td>Image Processing</td>
<td>Diagnostic Radiographer</td>
<td>In-house competency training</td>
</tr>
<tr>
<td>Administration of contrast</td>
<td>Diagnostic Radiographer</td>
<td>Competency in IV injection assessed by</td>
</tr>
<tr>
<td>agent</td>
<td>Radiologist</td>
<td>formal course or in-house</td>
</tr>
<tr>
<td>Routine CT QA</td>
<td>Diagnostic Radiographer</td>
<td>In-house competency training</td>
</tr>
<tr>
<td>CT QA (Routine or following</td>
<td>Clinical Scientists, and Clinical</td>
<td>Post-graduate training, appropriate</td>
</tr>
<tr>
<td>major scanner maintenance</td>
<td>Technologists (ABMU LHB Radiation</td>
<td>practical experience and In-house</td>
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<tr>
<td></td>
<td>Protection Service Staff)</td>
<td>competency training</td>
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<tr>
<td>Clinical evaluation</td>
<td>Consultant Radiologist</td>
<td>On FRCR training beyond part covering</td>
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<tr>
<td></td>
<td></td>
<td>IR(ME)R schedule 2 training</td>
</tr>
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</table>

*Where In-house competency training is required lists of training records of individuals able to act in these capacities will be kept in each area.
6.2 **SOP33B: Procedure for Identification of Individuals Undergoing a Medical Exposure**

**Purpose**
To ensure the correct identification of patients prior to exposure.

**Scope**
All CT examinations.

**Responsibilities**
The operator initiating the exposure is responsible for ensuring the final check of patient identity has been made before proceeding. The operator checking patient identity will adhere to this procedure.

**Procedure**
1. The operator will require the patient to complete and sign a Safety Questionnaire (Appendix 2) that gives details of his or her full name, date of birth and their address, consultant or GP and the area they are expecting to have imaged. Local Rules

2. The operator must undertake a positive ID check and therefore they must ask the patient to state their name, address and date of birth. These details must be checked against the request form and Safety Questionnaire, if there are any discrepancies these must be investigated before undertaking the examination.

3. If the operator is satisfied that they have the correct patient they will countersign the Safety Questionnaire under ‘Operator’s Signature’. this will be scanned into the patients records on Radiology Information System (RIS) for reference.

4. For patients unable to communicate through illness, physical or mental disability or language barrier, check identification bracelets or ask an escorting relative, carer or interpreter (REF ? SOP). A positive identification must be given.

5. If there is no escort or identification bracelet on a patient, who is unable to give their details, contact the referring department and ask for someone who can identify that patient, such as a nurse or relative, to visit and identify the patient. This must be recorded on the request form.

6. The person who checks the patient identity will sign the request form in the “patient ID checked by” box.
7. The same identification procedure will be used by Radiographers immediately prior to an intravenous injection of Contrast Media. (REF ? SOP)

8. A history of any previous relevant X-ray investigations should, whenever possible, be taken from the patient prior to carrying out the new procedure to correlate the clinical detail provided on the radiology request form to that patient. The RIS and Picture Archive and Communication System PACS should be checked in every patient contact to ensure up to date records and any previous radiology or information.

**Flow chart Appendix 3**

*Identification of Individuals Undergoing a Medical Exposure In CT*

*CIF*

---

Patient is asked to complete CT screening Form

- Yes
  - Form completed
    - Radiographer reviews form together with request form
    - Identification Bracelet present. Relative or Medical Officer available to give ID
    - Positive ID made
      - Radiographer signs screening form
      - Screening form scanned in to patient’s records
    - No procedure undertaken

- No
  - No procedure undertaken
  - Screening form scanned in to patient’s records
  - Unable to ID

---

WWORTH-SOP33aMCTinClinicalImagingV2.0-121026
6.3 **SOP33C: Procedure for Making Enquires of Females of Childbearing Age**

**Purpose**
To prevent unnecessary irradiation of a foetus from a medical exposure by ensuring enquiries with regard to pregnancy are made in an appropriate and consistent manner.

**Scope**
All women of childbearing age who are to undergo CT examinations of the abdominal and pelvic areas.

**Responsibility**
The operator initiating the exposure is **responsible for ensuring the final check of pregnancy has been made** before proceeding. The **operator** checking pregnancy will adhere to this procedure.

**Procedure**
1. The **operator** will require the patient to complete and sign a safety questionnaire that will include questions on pregnancy and Last Menstrual Period LMP.

2. If the patient states that she is NOT pregnant sign the “No” box in the Pregnancy Section on the Radiology Request Form and proceed with the exposure.

3. If the patient states that she IS pregnant:
   3.1 Contact the **referrer** to check if the procedure may be safely deferred.

   3.2 If the procedure **cannot** be deferred justification will only be provided by a Consultant Radiologist. Contact the Consultant Radiologist and record the outcome of the decision on the radiology request form.

4. If the patient states that she is **UNCERTAIN**:
   4.1 Review her given date of LMP. Record the date in the “LMP” box on the Radiology Request Form.

   4.2 For **HIGH DOSE PROCEDURES** (listed in Table 1)
• If the LMP date is within 10 days of the proposed examination date, proceed with the exposure.

• If the LMP date is over 10 days contact the referrer to check if the procedure may be safely deferred. If the procedure cannot be deferred request a pregnancy test must be arranged. If the pregnancy test is negative proceed with the exposure. If pregnancy test is positive the examination must not proceed until justification is provided by a Consultant Radiologist.

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<tbody>
<tr>
<td>CT Pelvis</td>
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<tr>
<td>CT Abdomen</td>
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<tr>
<td>CT Lumbar Spine</td>
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Table 1 High Dose Examinations*

*High dose procedures are identified in the document 'Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation. HPA March 2009'. (REF 9) These procedures could result in a foetal dose greater than 10mGy and an approximate doubling of the natural baseline risk of childhood cancer.

4.3 For LOW DOSE PROCEDURES (Any examination not listed in Table 1)

• If the LMP date is within 28 days of the proposed examination date proceed with the exposure.

• If the LMP date is over 28 days contact the referrer to check if the procedure may be safely deferred. If the procedure cannot be deferred a pregnancy test must be arranged. If the pregnancy test is negative proceed with the exposure. The negative pregnancy test must be recorded on the Radiology Request Form. If the pregnancy test is positive the examination must not proceed until justification is provided by a Consultant Radiologist which should be recorded on the request form.

5 For patients unable to communicate through illness, physical or mental disability or language barrier, all questions relating to pregnancy will be addressed to an escorting relative, carer or interpreter. (REF ? SOP)
CT CIF Pregnancy Flowchart

Female patient of child bearing age referred for CT scan

Pt completed CT Safety questionnaire
Are you pregnant?

No

Patient signs form and scan performed

Yes

Patient not scanned Refer back to Clinical Lead and Referring Clinician

Follow the 28 day rule for LMP

YES

CT low dose area

CT high dose area

Follow the 10 day LMP rule

No scan
### 6.4 SOP33D: Procedure for Justification / Authorisation of a Medical Exposure

**Purpose**
IR(ME)R requires every individual medical exposure to be justified and authorised in advance. This procedure states how that justification takes place and how the *operators* conducting a medical exposure are made aware of the fact that justification has occurred.

**Scope**
All CT examinations.

**Responsibility**
It is the responsibility of the *practitioner* to authorise each exposure only if it is justified and the responsibility of the *operator* to effect a medical exposure only once authorisation has been obtained.

**Procedure**
Consultant Radiologists are entitled in accordance with the IR(ME)R to be *Practitioners* for CT examinations.

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

- The objectives of the exposure.
- The direct health benefit to the individual.
- The individual detriment the exposure may cause; and
- The benefits and risks of alternative techniques which may meet the objectives with less or no detriment.

**The following matters will demand special attention:**

- Exposures on medico-legal grounds.
- Exposures with no direct health benefit to the individual being exposed; and
- Exposure of females who are, or may be pregnant.
• Urgent/out of hours exposures

• Children

If sufficient clinical information is not made available by the referrer the Radiology Request Form will be returned in the cases of non-urgent referrals. In the case of urgent referrals the practitioner will arrange for the referrer to be contacted to obtain the relevant information. The practitioner will arrange for the non-urgent Radiology Request Forms to be returned with a tick chart (appendix 5) identifying additional information required attached.

The practitioner authorises the exposure by signing the Radiology Referral Form. This is scanned into the patient records on RIS as a medico-legal document for future reference. Ref 5.
6.5 **SOP33E: Procedure for the Clinical Evaluation of a Medical Exposure**

**Purpose**
To identify the process and scope of Radiological Reporting.

**Scope**
All CT examinations.

**Responsibility**
Clinical evaluation is an *operator* task and it is the responsibility of the named Radiologist to report all examinations performed or directly supervised by them. The responsibilities of individuals involved in the process of reporting and matching these reports to a patient’s history held on the Radiology Information System (RIS) is described in the following procedure. All examinations recorded on RIS will have a Radiology Report. The Data Protection Act, Clinical Governance and Archiving SOP will be attired to.

**Procedure**

1. The Referral Form will be made available to the Radiologist who is to report the examination. Reporting may be done from the host modality directly or from the PACS workstation.

2. Reports will be generated on RIS and be performed using traditional transcription from audiotape by medical secretary or directly with voice dictation software.

3. When authorised on RIS a paper copy of the report is printed and sent to the *referrer*.

4. In addition to the paper report sent to the *referrer* the report is stored electronically within RIS and linked to images for that examination on PACS.

5. In cases where there is no report the request form will be resubmitted to the nominated Radiologist who will be responsible to ensure a report is completed.
6.6 **SOP33F: Procedure for the Assessment of the Patient Dose**

**Purpose**
To detail how patient dose indicators are recorded for each medical exposure.

**Scope**
Covers all CT examinations.

**Responsibility**
It is the responsibility of the operator who initiates the exposure to ensure that the appropriate patient dose indicator is recorded. This can be done by recording it themselves or checking that another operator has performed this task.

**Procedure**

1. The CT scanner will automatically record the CTDI$_{vol}$ and Dose Length Product (DLP) for the examination in the patient’s examination record which is stored and available of PACS.

2. Should a patient dose and risk assessment be required, the Superintendent Radiographer will contact the Medical Physics Expert and provide the appropriate dose indicator value and other relevant patient information.
6.7 SOP33G: Procedure for Setting and Monitoring Diagnostic Reference Levels (DRL)

**Purpose**
To set and review Diagnostic Reference Levels (DRLs) and to take corrective action and review levels when consistently exceeded.

**Scope**
CT examinations with nationally established DRLs.

**Responsibility**
The Superintendent Radiographer together with the Medical Physics Expert (MPE) will investigate excessive doses and implement corrective action. (Ref 10/11)

**Procedure**
1. At least once every three years the MPE will perform a patient dose audit, set DRLs and provide a list to the Superintendent Radiographer.

2. The Superintendent Radiographer will ensure the list of DRLs is displayed in the CT scanner control room. Appendix 6

3. For each examination the *operator* initiating the exposure will compare the dose indicator with the relevant DRL.

4. The *operator* initiating the exposure will make a record of any dose indicator exceeding the relevant DRL (for reasons other than large patient).

5. The Superintendent Radiographer will review the results at regular intervals and establish where DRLs are being consistently exceeded.

6. The Superintendent Radiographer together with the Medical Physics Expert (MPE) will investigate excessive doses and implement corrective action.
6.8 **SOP33H: Procedure for Accidental or Unintended Radiation Exposure**

**Purpose**
To ensure that all accidental and unintended exposures to patients or participants are properly investigated and recorded.

To ensure that reportable incidents are reported to the appropriate authority.

**Scope**
Covers all CT examinations.

**Procedure**

1. Any member of staff who suspects that an accidental, unnecessary or unintended exposure has occurred will, as soon as possible, record relevant information and report full details of the incident to the Superintendent Radiographer who will arrange for an investigation to be carried out immediately and for an incident report to be completed.

2. Patients who undergo a procedure that was not intended, as a result of mistaken identification or other procedural failure, and consequently have been exposed to an ionising radiation dose, must be considered as having received an unintended dose of radiation.

3. If the person reporting the incident has reason to believe it was caused by a radiation equipment fault, that person will advise other staff not to use the suspect equipment until it has been checked. The Superintendent Radiographer will arrange for an assessment of the equipment to be made and will not allow it to be used for medical exposures until it is demonstrated that its performance is reliable and within recommended QA standards.

4. The Superintendent Radiographer will seek advice from the Radiation Protection Adviser on the estimation of dose, risk assessment, the grading of the incident, and the need to notify the relevant Authority. Most radiation incidents are not considered to be serious adverse incidents because of the low risk of potential health effects. The RPA will provide advice on this categorisation for individual cases.

5. The local investigation report will include:
6. The RPA will advise the Head of College who will ensure the incident is reported directly to the relevant authority unless the investigation shows beyond reasonable doubt that no overexposure occurred or the patient dose was not much greater than intended on the basis of HSE Guidance.

Notification to the relevant authority will be provided within 10 working days the incident. If the final report cannot be sent within that period the RPA will send a preliminary communication to the relevant authority stating that a formal report will follow.

Patients who have been exposed to a dose of radiation much greater than intended, shall be informed of the incident, unless it can be justified not to do so. The Clinical Lead shall decide how, when and by whom the patient is notified. Decisions not to inform the patient or the patient’s representative or parent/guardian shall be clearly recorded in the patient’s case notes.

The Superintendent Radiographer will be responsible for

- A general description of what happened, dates, why the accident arose and the names of staff involved with a description of their involvement

- Copies of any statements taken from staff

- Copies of relevant documents/papers associated with the incident (e.g. the Radiology Request Form)

- Copies of relevant IR(ME)R procedures

- An assessment of the extra radiation dose resulting from the incident and associated long and short term effects or risks to the patient

- Whether the patient (or relevant other person) has been informed, and if not the reasons why and whether a complaint will be made.

- Details of any similar incidents or near misses in the past involving the same staff or within the same department.

- Follow-up action taken after the incident to reduce the likelihood of re-occurrence and lessons learnt.
maintaining records of all incidents. Records of notifiable incidents (IRR99) will be kept for 50 years on PMS and University H&S Incident File.
6.9 **SOP33I: Procedure for the Exposure of Individuals Participating in Research Studies**

**Purpose**

To ensure that all clinical research trials restrict any dose of ionising radiation to the minimum required to achieve the intended clinical objective and comply with regulatory requirements Integrated Research Application System (IRAS).

**Scope**

All PI and Chief Investigators should follow the procedure to ensure restricted use of Ionising Radiation to Human Subjects.

**Procedure**

1. All research studies involving patients or volunteers that are carried out within the NHS must be approved by the National Research Ethics Service. All applications to this body are made using the IRAS (Integrated Research Application System) – [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk) (see WWORTH SOP14a Ethics Approval and WWORTH SOP14b Applying for NHSR&D approval)

2. Persons completing this form must follow the NRES guidance, ‘Approval for research involving Ionising radiation. 2008. This is available via the NRES website at: [http://www.nres.npsa.nhs.uk/applications/guidance/#ionisingrad](http://www.nres.npsa.nhs.uk/applications/guidance/#ionisingrad)

3. Adherence to this guidance will ensure that the research is conducted in accordance with the IR(ME)R.

4. All applications must also be submitted to the Host NHS Organisation R&D Department for approval in accordance with NHS policies and procedures which are consistent with the Research Governance Framework for Health & Social Care. NHS R&D Permission will not be granted without evidence of a favourable ethical opinion & scientific peer review.

5. Locally within ABMU Health Board, all proposals for clinical trials involving cancer treatment are handled on behalf of the Chief Investigator (CI) or local Principal Investigator (PI) by a team of Research Nurses at the Clinical Trials Unit at Singleton Hospital. It is very rare for ABMU to be the lead Sponsor for a Cancer Trial, thereby responsible for the full application to the main REC. Almost always, the trials will be either Sponsored by Industry or Non-Commercial Research Charities. It is therefore, the Site Specific
Information Form (SSIF) that is completed from a local perspective. The SSIF and full submission dataset is sent for Health Board R&D Permission. As part of this process, the Research Nurses will ensure that the local IR(ME)R practitioner and the Medical Physics Expert are consulted as required by the guidance.

6. The CI or PI for the research will seek prior advice on doses and risks from the Radiation Protection Adviser or Medical Physics Expert. For the SSIF the Medical Physics Expert will confirm whether the protocol can be performed at the site within the estimated dose range stated in the main REC application form.

7. The CI or PI will ensure that justification of the exposure is discussed with the practitioner who must be identified in the application. For research exposures this will usually be a Consultant Radiologist, a Consultant Clinical Oncologist.

8. 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 benefit to society provided in Table 1.

Table 1

<table>
<thead>
<tr>
<th>Benefit to Society</th>
<th>Dose Constraint (mSv)(^a)</th>
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<tr>
<td>Minor</td>
<td>&lt; 0.1</td>
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<tr>
<td>Intermediate</td>
<td>0.1 – 1</td>
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<tr>
<td>Moderate</td>
<td>1 – 10</td>
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<tr>
<td>Substantial</td>
<td>&gt; 10</td>
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\(a\). These figures can be increased by a factor of 5-10 for those over 50 years. In the unlikely event of approval of research on children they should be reduced by a factor of 2 or 3.

9. Where there is a diagnostic or therapeutic benefit from the radiation exposure the above dose constraints are not appropriate but an individual target level of dose will be specified in the submission. Examples of this type of exposure are therapeutic exposures and experimental diagnostic imaging.

10. The CI or PI will ensure that submission to the REC and R&D Department specifies for all exposures required by the research protocol, whether or not they are over and above those required for normal clinical management, the appropriate dose constraint or target dose and corresponding risks. This will be documented in the Site File.
11. The CI or PI will satisfy him/herself that the individuals concerned participate voluntarily in the research programme and ensure that they have been informed in advance about the risks of the exposure.

12. In order facilitate the above actions the CI/PI/Research Nurse will send a copy of the approved research protocol to the Superintendent Radiographer and Consultant Radiologist of the site where the exposure is to be carried out indicating which exposures are additional to standard clinical practice.

13. The Superintendent Radiographer and Consultant Radiologist of the site carrying out the exposures will maintain a register of approved research studies including details of the exposures and dose constraints and will ensure that the total dose from all exposures associated with the protocol does not exceed the dose constraint or target dose.

14. The referrer who signs requests for research exposures will ensure that reference to the research study is included in the clinical details.
6.10 **SOP33J: Procedure for Document Quality Assurance**

**Purpose**
To ensure that quality assurance programmes for the regular review and control of all Employers procedures are followed.

**Scope**
All Employers procedures and examination protocols.

**Procedure**
1. The Superintendent Radiographer will ensure that IR(ME)R procedures and protocols are reviewed at least once every two years and immediately following the introduction of new equipment and/or techniques.

2. Changes to examination protocols will only be made by Superintendent Radiographer.

3. The Superintendent Radiographer will maintain and update the equipment inventory list.

4. All IR(ME)R procedures will have file name, revision number, page number and total number of pages in the footer. The front page of each IR(ME)R procedure will also contain the following information:

<table>
<thead>
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<tbody>
<tr>
<td>Revision Number</td>
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<tr>
<td>Issue Date</td>
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<tr>
<td>Review Date</td>
<td></td>
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<tr>
<td>Author:</td>
<td></td>
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<td>Approved by:</td>
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**REVISION HISTORY**

<table>
<thead>
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<th>Comment</th>
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A master copy of the IR(ME)R procedures will be kept by the Superintendent Radiographer Clinical Imaging facility.
6.11 **SOP33K: Procedure for Ensuring that the Probability and Magnitude of an Accidental or Unintended Dose to the Patient are Reduced so far as is Reasonably Practicable**

**Purpose**
This is to ensure accidental or unintended Radiation Does should be managed to that any probably can be minimized.

**Scope**
All staff using the CT scanner should follow to procedure to reduced radiation exposure.

**Procedure**

1. Departmental staff meetings, during which radiation protection information is disseminated, are held regularly and minuted. These meetings include Supt/ manager meetings, Directorate Meetings and general staff meetings.

2. The identity of the patient is checked prior to any radiation exposure, following IR(ME)R procedure 2.

3. All equipment is subject to regular preventative maintenance and independent radiation safety and performance assessment, as required by IRR99. See also Local Rules, section 11.

4. The Clinical Imaging Facility operates an equipment QA programme.

5. CT equipment faults are logged and reported to the Superintendent Radiographer.

6. Equipment that is exhibiting faults likely to cause patient overexposure must be taken out of use until repair by a service engineer, and written confirmation obtained that the unit is fit for clinical use. Equipment QA checks must also be undertaken before the equipment is again used clinically.

7. All staff receive appropriate in-house training on the operation of equipment.

8. All untoward incidents are reported to the RPA via the RPS. Subsequent advice is sought from the RPA in order to estimate the
dose and associated risk factors.

9. All radiation incidents are reported and investigated.

10. The cause of radiation incidents are reviewed and appropriate action taken to minimise the risk of recurrence.

11. Care is taken at all times whilst examining patients to select the most appropriate examination settings and operate it in accordance with manufacturer’s instructions and IR(ME)R procedures.
6.12 **SOP33L: Procedure for the Provision of Imaging Protocol and Standard Exposure Factors**

**Purpose**
To identify the procedure for the provision of imaging protocols (standard projections/image sequences) and the setting of standard exposure factors, following ‘Making the Best Use of Clinical Radiology Services. Royal College of Radiologists. 2012 (8)

**Scope**
All CT examinations.

**Procedure**
1. Standard *imaging protocols* are agreed by the Lead Consultant Radiologist and documented by the Superintendent Radiographer. No alterations can be made to these protocols without consent of the Consultant Radiologist.

2. Standard *exposure factors* for each type of CT examination are stored within the scanner’s anatomical programme lists on the CT scanner.

3. In cases where *exposure factors* appear to fluctuate, the Superintendent Radiographer will liaise with the ABMU LHB Radiation Protection Service and the service provider for advice. Once advice has been received appropriate action will be taken.

4. Any adjustment to the programmed *exposure factors* must be authorised by the Superintendent Radiographer.
6.13 **SOP33M: Procedures to be observed in the case of medico-legal exposures**

Presently this procedure is not undertaken at this time in the CIF Unit, but it will be reviewed if and when this procedure is undertaken.

**Purpose**

To identify the process for carrying out a medico-legal exposures.

**Scope**

This procedure applies to radiation exposures performed for insurance or legal purposes without a medical indication. The following categories are included:

- **Medico-Legal.** These are usually required by a Court with instructions received from a Solicitor in assessment of personal injury claims.
- **Medical examinations required of defendants in court cases.**

**Responsibility**

The *practitioner* will be a Consultant Radiologist for all procedures. The *practitioner* is responsible for 1 to 6 below. The *operator* carrying out the examination is responsible for 7.

**Procedure**

1. No medico-legal exposure will be performed unless it can be justified, as showing a net benefit either to the individual or to society.

2. Referrals will only be accepted from GMC registered medical doctors.

3. There must be sufficient information from the *referrer* to allow justification.

4. If the medical exposure is for a child or a pregnant woman, then further information will be required from the *referrer* before justification.

5. The procedure will only be justified if it is not possible to use alternative techniques involving no or less exposure to ionising radiation.
6. Checks must 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.

7. Once justified and authorised, medico-legal exposures will be performed as for other standard medical exposures.
7 Training Plan

All WWORTH staff involved with trials must undertake the appropriate generic and trial-specific training to ensure that they meet with the specific employers' mandatory training requirements and the specific requirements of the trial. For example, for SU staff, all new employees must attend induction, fire and safety training (as well as role-specific training courses, e.g. laboratory safety). For new staff, additional training requirements should be identified alongside the specific role requirements and the WWORTH Unit Manager should make provision for the new staff member to attend the necessary courses as soon after appointment as is practicably possible.

It is the responsibility of the WWORTH Unit Manager (alongside the CI or TM) to identify all the SOPs that are relevant to a specific trial and in which the new member of staff should be trained. The WWORTH UM or the SOP author will provide group training for trial staff and/or one-to-one training, as required for new staff in relation to the specific SOPs identified. Training records should be filed both by the main employer and the staff member, in accordance with the specific employer requirements. Trial specific training should be filed in TMF or TSF as appropriate and every individual involved in a trial should have an individual training record.

Where the tasks specified in the individual SOPs are delegated to WWORTH staff, CIs/PIs or TMs, these delegated staff must ensure that they have attended a training course on GCP and keep up-to-date through attending refresher courses.

It is the responsibility of the CI/PI to ensure that all staff allocated duties on the study delegation log template of responsibilities are suitably trained in the activities linked to those duties (see WWORTH SOP16 Site Setup).

Each trial should maintain a central training log and ensure that WWORTH has access to that log, not least to integrate the logs of staff who work on more than one trial. Similarly trials should ensure that each site maintains a local training log, not least to integrate the logs of staff who work for more than one sponsor.

8 References


5. Medical and Dental Guidance Notes: A good practice guide on all aspects of ionising radiation protection in the clinical environment Institute of Physics and Engineering in Medicine 2002 York ISBN 1 903613 09 4

6. Health and Safety under the Health and Safety at Work etc Act 1974 (HSW Act)


9. High dose procedures are identified in the document ‘Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation. HPA March 2009’


13. Successful health and safety management HSG65 (Second edition)  
HSE Books 1997 ISBN 0 7176 1276 7

14. The HSE Criteria of Competence is contained in the HSE statement on  
Radiation Protection Advisers at  
www.hse.gov.uk/hthdir/noframes/state.htm

15. Fitness of equipment used for medical exposure to ionising radiation  
PM77 (Second edition) HSE Books 1998 ISBN 0 7176 1482 4

9 Related SOPs

All other WWORTH SOPs, notably strategic SOPs on sponsorship of trials  
typically by Swansea University) and the adoption of new and existing trials  
by WWORTH.

10 Appendices

Appendix 1 CT Local Rules  
Appendix 1a Appointed Officers  
Appendix 1b Duties of the Radiation Protection Supervisor  
Appendix 1c Dose Limits (IRR99)  
Appendix 1d Staff Circulation List  
Appendix 2 Safety Screening Form CT- Patient questionnaire  
Appendix 3 Flow Chart 1  
Appendix 4 Flow Chart 2  
Appendix 5 CIF Return Form  
Appendix 6 CT Dose Reference Level
Appendix 1: CT Local Rules

Swansea University
College of Medicine

LOCAL RULES FOR SAFE USE OF IONISING RADIATIONS
COMPUTED TOMOGRAPHY (CT)

These Local Rules have been drawn up to conform with the requirements of the Ionising Radiations Regulations 1999 and associated Codes and Guidance. All signs, symbols and posted notices which relate to radiation protection also form part of these Local Rules.

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<tbody>
<tr>
<td>Simon Evans</td>
<td>Radiation Protection Adviser</td>
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<tr>
<td>Paola Griffiths</td>
<td>Radiation Protection Supervisor</td>
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<td>Richard Hugtenburg</td>
<td>Radiation Protection Supervisor</td>
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<tr>
<td>Steve Conlan</td>
<td>College Radiation Protection Supervisor</td>
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LOG OF REVIEWS OF LOCAL RULES
BY RADIATION PROTECTION SUPERVISOR

The rules will be reviewed annually by the Radiation Protection Supervisor (RPS) who will sign below if no changes are required. If amendments are considered to be necessary these will be sent to the Radiation Protection Adviser (RPA) for consideration. When the amendments have been agreed the rules will be re-issued and will be authorised by both the RPS and RPA by signing the front page.

The above rules have been reviewed by the RPS and are satisfactory.

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SECTION 1: INTRODUCTION

1.1 These local rules have been prepared to satisfy the Ionising Radiations Regulations 1999 (IRR99). By following these rules you will be able to work safely and comply with IRR99. Your annual radiation doses should be well below legal limits for adult workers and in most cases will be less than the limit for members of the public (Appendix 3).

1.2 Separate procedures relating to medical radiation exposures have been prepared to comply with the Ionising Radiation (Medical Exposures) Regulations 2000 (as amended) with which you should be familiar.

1.3 All members of staff who may be exposed to ionising radiation during the course of their work must be familiar with those sections of the Local Rules that apply to them and should sign a statement to this effect (Appendix 4). The following staff groups are required to read these rules:

- Radiographers and Student Radiographers
- Radiologists
- College staff operating the X-ray equipment for non human studies

1.6 The following groups are required to read the Systems of Work which are displayed on the X-ray room entrance door:

- Domestic and General Maintenance staff
- Visitors and Porters
- X-ray engineers and ABMU LHB Radiation Protection Service staff (who are expected to work to their own Local Rules).

SECTION 2: RESPONSIBILITIES AND PERSONNEL

2.1 Your Responsibility

2.1.1 If you work with ionising radiation you have a duty to work carefully and safely, exposing neither yourself nor other persons to radiation unnecessarily. For this reason you must become familiar with the Local Rules. Please read them carefully. You will be required to sign a statement agreeing to act in accordance with them.

2.1.2 You must

- not intentionally misuse X-ray equipment
- not interfere with X-ray equipment unless you have good reasons for doing so.
- use protective equipment and personal dosimeters when provided
- report any defects in protective equipment, or malfunctions in radiation equipment, to the Radiation Protection Supervisor (see 2.2) or Line Manager as soon as possible.
2.1.3 If you become pregnant, it is important that you notify your Line Manager in writing as soon as possible (see section 10).

2.1.4 Any matters of radiation protection may be brought ultimately to the attention of your Employer, but in the first place should be discussed with your departmental Radiation Protection Supervisor or Line Manager. Matters may also be brought to the attention of or discussed with the Radiation Hazards sub-committee of the University Health and Safety Committee.

2.2 Radiation Protection Supervisor (RPS)

2.2.1 The Employer has appointed an RPS to assist it in complying with the IRR99. In particular the RPS should ensure that, as far as possible, the protective measures laid down in the Local Rules are followed by any staff working with ionising radiation.

2.2.2 The names of the Radiation Protection Supervisor relating to X-ray work is given in Appendix 1.

2.2.3 For the duties of the Radiation Protection Supervisor see Appendix 2.

2.3 Radiation Protection Adviser (RPA)

2.3.1 The Employer has to consult an RPA on matters relating to IRR99 such as controlled areas, periodic examination of engineering controls, prior risk assessments, Local Rules, quality assurance programmes and radiation incidents etc. Details of the RPA appointed by the Employer is given in Appendix 1.

SECTION 3: CLASSIFICATION OF AREAS

3.1 Controlled Areas

The Employer has identified areas on its premises where people need to follow special working procedures to ensure that they do not receive significant radiation doses. These areas are called controlled areas. Unclassified staff and visitors may enter in these areas only under a written system of work (See Systems of Work in Section 4 and 5).

The CT scanner room is a controlled area (defined by red boundary below).
3.2 **Means of Restricting Access**

Warning notices and lights at the entrances to the CT scanner room. Locks on main entrance CT scanner room doors.

3.3 **Supervised Areas**

There are no supervised areas outside the controlled area.

**SECTION 4: SYSTEMS OF WORK FOR CT IMAGING STAFF**

**4.1 General**

4.1.1 Do not operate the CT scanner unless you are adequately trained to do so.

4.1.2 Take note of all warning signs and do not enter a room when the X-ray warning light outside the room is illuminated.

4.1.3 Remain within the protected control area when the X-ray beam is on.

4.1.4 Keep doors closed during X-ray exposures.

4.1.5 If you have been provided with a personal radiation dosemeter, wear it in the approved manner.
4.2 Staff operating CT equipment

4.2.1 Only HPC Registered Radiographers are permitted to use the CT scanner for human studies.

4.2.2 Lock the main doors giving access from the waiting area prior to scanning.

4.2.3 Check that all exposure parameters are correct before carrying out an exposure.

4.2.4 During tube “warm-up” remain at the control desk and ensure no-one enters the CT scanner room.

4.2.5 Ensure that no one other than the individual to be scanned will be in the primary X-ray beam.

4.2.6 Remote injection facilities should be used whenever possible.

4.2.7 Although the CT scanner has an exposure switch which does not have to be pressed throughout the exposure, the control panel must be manned during the scan sequence.

4.2.8 When necessary, give verbal notification to indicate when X-rays are about to be emitted, thus enabling all appropriate personnel to retire to safe areas.

4.2.9 At the cessation of activities, disconnect the equipment from the electrical supply to allow safe access for domestic and maintenance staff.

LOCAL RULES FOR RADIATION SAFETY

SECTION 5: SYSTEMS OF WORK FOR NON-IMAGING STAFF

READ THESE INSTRUCTIONS BEFORE ENTERING THIS ROOM

DOMESTIC AND GENERAL MAINTENANCE STAFF

1. Do not enter the room unless the yellow ‘controlled area’ sign is OFF. If in doubt, contact the radiographer.

2. Whilst in the room do not adjust any of the controls.

3. If it is necessary for cleaning or maintenance to be carried out while the electricity supply is connected to the CT scanner obtain permission from the radiographer and follow the instructions given.
VISITORS AND PORTERS

1. Do not enter the room without the permission of the radiographer.
2. Whilst in the room you must follow the instructions of the radiographer.

X-RAY ENGINEERS AND ABMU LHB RADIATION PROTECTION SERVICE STAFF

1. Report to the radiographer-in-charge before commencing work and follow the procedure for hand-over and hand-back.
2. Follow the radiation safety procedures provided by your employer.
3. Keep doors closed during exposures.
4. Remain in the protected (control) area during exposures unless the nature of your work precludes this, in which case, wear protective clothing.
5. If it is necessary to disable the warning lights at room entrances, ensure that entry is prevented (e.g. by locking doors and/or the use of NO ENTRY signs).
6. Inform the radiographer-in-charge of any modification to or maintenance of the equipment which may alter the radiation output or quality, or otherwise affect protection. In addition attach a notice to the equipment drawing attention to the modification or maintenance.

SECTION 6: NEW CT INSTALLATIONS OR PROCEDURES

6.1 The RPS should ensure that plans for new installations are submitted to the RPA for advice and approval. The RPS should also ensure that a critical examination, commissioning tests and prior risk assessment are completed before the new facility begins operation.

6.2 The RPS should ensure that the RPA is informed of any X-ray tube changes in order for appropriate radiation safety and performance tests to be arranged before the scanner is used with patients.

6.3 If a new procedure is introduced the RPS must ensure that a risk assessment is carried out in liaison with the RPA before the procedure is introduced.

SECTION 7: CONTINGENCY PLAN

7.1 Exposure fails to terminate

7.1.1 Staff operating the CT equipment
If the X-ray warning indicator stays on after releasing the exposure button:

- **Immediately** turn off the power supply at the mains switch.
- Attach a notice to the control panel saying that it must not be used
- Inform the Radiation Protection Supervisor of the incident.
- Do not use the equipment until it has been repaired.

### 7.1.2 RPS

- Inform the RPA and Head of College of the incident.
- Contact the CT equipment engineer and ensure that the equipment is not used until it has been repaired.

### 7.1.3 Staff who operate the CT equipment must establish the location of the main power switch and ‘emergency-off’ switches before using the equipment.

### SECTION 8: SUSPECTED HIGH EXPOSURE/RADIATION INCIDENT

#### 8.1 General

If any member of staff believes that they, or any other person including the patient, may have been involved in an incident, they should report the incident to the RPS immediately. A record must be made of the exposure settings at the time of the incident and brief details of the events leading up to the incident.

The RPS should inform the RPA. The RPS should also carry out an immediate investigation - in conjunction the Radiation Protection Adviser if necessary. The RPA will advise on whether or not Health Inspectorate Wales need to be notified.

### SECTION 9: PERSONAL RADIATION MONITORING

#### 9.1 General

##### 9.1.1

The dosemeter MUST be worn at chest or waist level (under a protective apron if worn in the CT scanner room during exposures).

##### 9.1.2

Keep the dosemeter away from excessive heat, moisture or chemical fumes.

##### 9.1.3

Be responsible for its proper use and replacement at the specified time.

##### 9.1.4

Inform the RPS if you suspect that:

- Your dosemeter (or holder) is damaged, accidentally exposed to radiation or has been exposed to excessive heat, moisture or chemicals
- You have lost or misplaced your dosemeter (so another one can be issued)
9.1.5 If you have been issued with a personal radiation dosemeter you MUST NOT:

- Wear it whilst you are undergoing a medical radiation exposure yourself.
- Wear a dosemeter which has been specifically issued to someone else.

9.1.6 Records of doses are kept by the RPS and staff may ask to see their records.

9.2 Local investigation level

Most staff should routinely receive very small doses. A local investigation level of 2mSv in a year has been set for all staff using the CT scanner. The departmental manager must carry out a formal investigation if the effective dose received in a calendar year exceeds the investigation level.

9.3 Regular review of personal monitoring results

Personal radiation monitoring results are reviewed annually by the Radiation Hazards sub-Committee. In addition results are reviewed throughout the year by the RPS and RPA. Any results corresponding to more than 1/40th of any dose limit are discussed with a view to taking action to restrict future exposure.

SECTION 10: INFORMATION FOR FEMALE AND PREGNANT STAFF

10.1 As an employee of the University your work may require you to enter areas where radiation may be present because X-ray equipment is in use. IRR99 require employers to inform all their female staff who are engaged in work with ionising radiation of the possible hazards arising from radiation exposure, particularly to an unborn child.

10.2 The risks to the unborn child are very small. If you wear a dosemeter, your dose will already be known. For diagnostic X-ray work the dose to the foetus is about one half of the dose recorded by the dosemeter. For many years it has been the practice to minimize the radiation dose to staff during pregnancy to avoid any unnecessary risk to the baby. It is highly unlikely that staff, whether pregnant or not, will exceed 1mSv, even in a whole year. For comparison, on average, each member of the UK receives more than 2mSv every year from natural background radiation. During pregnancy, your baby will receive about 1 mSv from background radiation. The added exposure at work should be no more than this, and in practice, is likely to be considerably less.

10.3 If your work involves the use of X-rays and you become pregnant it is important that you notify your Line Manager (and hence your employer) in writing as soon as possible.

10.4 Once notified, your Line Manager must take steps to ensure that the dose to your baby from radiation received at work will be less than 1 mSv. In most cases you will
be able to continue your normal duties. You should not take on any extra duties that would increase your whole body dose during pregnancy.

10.5 Further information is available in the HSE leaflet "Working safely with ionising radiation: Expectant and Breast Feeding Mothers". A copy of this is available in the department.

SECTION 11: EQUIPMENT FAULTS, MAINTENANCE & MODIFICATIONS

11.1 The radiographer must record all faults and the outcome of remedial action in the CT fault book.

11.2 For routine maintenance a controlled area handover form must be completed prior to the CT Scanner room being made available to contractors (e.g. X-ray engineers).

11.3 X-ray engineers, must inform the Radiographer of any maintenance undertaken on, or modifications to, X-ray equipment which might have altered the X-ray output, beam quality or radiation protection of the X-ray tube. The RPS will then contact the ABM Radiation Protection Service for advice and appropriate radiation safety and performance assessment.

11.4 The RPS will ensure that the equipment is not returned to clinical use until any recommended performance assessment has been completed and that any necessary changes to operating procedures and examination protocols are made.

SECTION 12: ARRANGEMENTS FOR TESTING WARNING LIGHTS & PERSONAL PROTECTIVE EQUIPMENT

12.1 The operation of door warning lights and X-ray warning lights are examined yearly as part of the ABM Radiation Protection Service radiation safety and performance assessment. In addition staff using the CT scanner should report any malfunction immediately to the RPS.

12.2 Protective aprons, where provided, should be examined radiographically at least once a year and a record kept by the RPS.

SECTION 13: ARRANGEMENTS FOR ENVIRONMENTAL RADIATION MONITORING

13.1 Monitoring is carried out by the ABMU LHB Radiation Protection Service in on a 3 yearly cycle.

13.2 In addition, monitoring is carried out following significant changes in workload, techniques, or equipment. The RPS is responsible for notifying the ABM Radiation Protection Service.
Appendix 1a: Appointed Officers

Radiation Protection Supervisors

Mrs Paola Griffiths  
Superintendent Radiographer  
Clinical Imaging Suite  
ILS2  
Swansea University  
T: 01792 606739  
E: paola.a.griffiths@swansea.ac.uk

Dr Richard Hugtenburg  
Senior Lecturer in Medical Physics  
Institute of Life Science  
College of Medicine  
Singleton Park,  
Swansea University  
E: R.P.Hugtenburg@swansea.ac.uk

Dr Steve Conlan  
Centre for NanoHealth Director  
Institute of Life Science  
College of Medicine  
Singleton Park,  
Swansea University  
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Radiation Protection Advisers

Mr Simon Evans and Mr James Roberts  
Radiation Protection Service  
Department of Medical Physics and Clinical Engineering,  
Singleton Hospital, Swansea SA2 8QA.  
T: 01792 285840/ 205613  
E: simon.evans@wales.nhs.uk  
          james.roberts@wales.nhs.uk

Appointed Doctor

None appointed.

The University has not requested that the HSE appoint an appointed doctor because it does not employ any classified workers. In the event of, e.g., an employee receiving an overexposure the Health Board would need to notify the HSE which can be done through the Employment Medical Advisory Service (EMAS). If requested, EMAS can then arrange for the services of an appointed doctor or medical adviser.
Appendix 1b: DUTIES OF THE RADIATION PROTECTION SUPERVISOR

Duties

1. Supervise the work with CT equipment so that, as far as possible, such work is in accordance with these Local Rules.

2. Be familiar with the requirements of the local rules and relevant parts of the IRR99, Approved Code of Practice and non-statutory guidance.

3. To ensure that on relinquishing the post of RPS, the Head of College of Medicine is informed.

Additional Tasks undertaken by the RPS but which remain the responsibility of the manager (if not same person)

4. To assist the line manager in ensuring that the Local Rules are read and understood by those persons to whom they apply, and as far as possible, to ensure compliance.

5. To organise and administer the assessment of doses to staff by means of personal dosimeters by:
   a) ensuring that dosimeters when issued, are worn in the approved manner, and changed at agreed times by all the appropriate staff,
   b) preparing and reviewing a list of staff to be monitored in conjunction with the RPA
   c) retaining records of the dose assessment in the department for 2 years (for non-classified persons).
   d) keeping the doses received by staff under review and if necessary notify the RPA and Head of College if:
      - any staff exceed the local dose investigation level (See Section 9).
      - any staff will need to be classified (see Appendix 3).
   e) informally investigating any effective doses received by individuals in a single monitoring period greater than 1.0mSv

6. To report to the Line Manager, the Radiation Hazards sub-committee and the RPA details of any excessive doses received by personnel, to carry out investigations in conjunction with the RPA when appropriate, and to make special reports of potential hazards or of incidents.

7. To assist the Head of College with prior risk assessments

8. To assist the Department Manager in maintaining a log of details of any maintenance undertaken on, or modifications to, X-ray equipment that might alter the X-ray output, beam quality or protection of the tube. Where significant changes in X-ray output or protection of the tube might occur, the RPS should inform the department staff and the RPA.

9. To arrange for any protective clothing used in the X-ray room to be examined at regular intervals, both visually and radiographically, and to record the findings.

10. For any proposed new X-ray installation or new techniques, to assist the Department Manager in arranging
    a) for the RPA to have plans of the change for the appropriate advice and approval.
    b) the completion of a prior risk assessment and
c) for a radiation safety assessment before bringing new equipment into operation.

11. To ensure that warning lights are operating correctly and that warning notices are correctly displayed.
Appendix 1c: DOSE LIMITS (IRR99)

<table>
<thead>
<tr>
<th>Person</th>
<th>Annual dose limit in mSv</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Whole body</td>
</tr>
<tr>
<td>Employee aged 18 yrs or over</td>
<td>20</td>
</tr>
<tr>
<td>Trainees &lt;18 years</td>
<td>6</td>
</tr>
<tr>
<td>Public</td>
<td>1</td>
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</tbody>
</table>

Additional dose limits

Abdomen of female employee of reproductive capacity: 13 mSv in any 3 month period

Classified Persons

Staff must be designated as classified persons if they are likely to receive more than 3/10 of the employee (aged 18yrs or over) limits. There are no classified persons employed by the Health Board.
### Appendix 1d: Staff Circulation List

**I have read and understood these local rules**

<table>
<thead>
<tr>
<th>2.1.1.1</th>
<th>NAME</th>
<th>SIGNATURE</th>
<th>DATE</th>
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</table>
**Appendix 2: CT Safety Screening Form – Patient questionnaire**
CT Safety Screening Form

Safety Questionnaire for Patients Undergoing CT Scanning
CT scanning involves x-rays, and so has the usual risks associated with ionising radiation. Many CT examinations involve you having a contrast medium (dye) injected into a vein in order to increase the amount of information obtained from the scan. The injection usually causes nothing more than a warm feeling passing around your body although there is a slight risk of an allergic reaction. Your doctor has considered these risks and believes the benefits of this scan outweigh the small risks associated with this examination. Please complete the following information:

Surname: ................................................................ Forenames: ..........................................................
Address: ...........................................................................................................................................
Date of Birth: ...............................................
Telephone Number: ................................................. Consultant: ..........................................................

1. Have you had an x-ray contrast agent injected before?
   YES / NO

2. **If you answered YES, did the injection cause you any problems?**
   YES / NO
   **Are you allergic to iodine?**
   YES / NO

3. **Are you diabetic?**
   YES / NO
   **If you answered YES, do you take metformin?**
   YES / NO

4. **Do you suffer from asthma?**
   YES / NO
   **If you answered YES, do you take regular medication?**
   YES / NO
   **Have you ever been hospitalised during an episode of asthma?**
   YES / NO

5. **Do you have any kidney problems?**
   YES/ NO

6. **Do you have any history of cardiovascular disease (heart problems)?**
   YES / NO

7. **Do you suffer from Myeloma?**
   YES/ NO

8. **Do you suffer from multiple allergies?**
   YES / NO

9. **Have you had a similar examination to the one you are booked for today?**
   YES / NO

If yes, when and where did the examination take place?
Appendix 3: Flow Chart 1
Identification of Individuals Undergoing a Medical Exposure In CT
CIF

Patient is asked to complete CT screening Form

Form completed

Yes

Radiographer reviews form together with request form

Positive ID made

Radiographer signs screening form

Screening form scanned in to patient’s records

No

Identification Bracelet present. Relative or Medical Officer available to give ID

Yes

No procedure undertaken

No

Unable to ID
Appendix 4: Flow Chart 2

Female patient of child bearing age referred for CT scan

Pt completed CT Safety questionnaire
Are you pregnant?

Yes

Follow the 28 day rule for LMP

unsure

No

Patient signs form and scan preformed

Patient not scanned
Refer back to Clinical Lead and Referring Clinician

CT low dose area

CT High Dose Area

Follow the 10 day LMP rule

Yes

No scan

No

CT CIF Pregnancy Flowchart
Appendix 5: CIF Return Form

SWANSEA UNIVERSITY
COLLEGE OF MEDICINE

CLINICAL IMAGING FACILITY

Date: ........................................

This Radiology Request Form is being returned because:

- It has incomplete patient details
- It has illegible patient/clinical details
- It does not contain sufficient clinical details
- It is not compatible with RCR guidelines
- Please discuss with Consultant Radiologist
- Other: ..........................................................

Signed: ........................................

Clinical Imaging Facility
College of Medicine
Appendix 6: CT Dose reference Level

National Reference Doses

<table>
<thead>
<tr>
<th>Examination (Clinical Indication)</th>
<th>CTDL$_{50}$ (mGy)</th>
<th>CTDL$_{vol}$ (mGy)</th>
<th>DLP (mGy.cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Head (acute stroke):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior fossa</td>
<td>10</td>
<td>100</td>
<td>-</td>
</tr>
<tr>
<td>Cerebrum</td>
<td>65</td>
<td>65</td>
<td>-</td>
</tr>
<tr>
<td>Whole exam</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chest (lung cancer or metastasis):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>18</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>Liver</td>
<td>19</td>
<td>14</td>
<td>-</td>
</tr>
<tr>
<td>Whole exam</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chest Hi res. (diffuse lung disease):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole exam</td>
<td>50</td>
<td>7</td>
<td>580</td>
</tr>
<tr>
<td>Abdomen (liver metastasis):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole exam</td>
<td>20</td>
<td>14</td>
<td>470</td>
</tr>
<tr>
<td>Abdomen &amp; pelvis (abscence):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole exam</td>
<td>20</td>
<td>14</td>
<td>560</td>
</tr>
<tr>
<td>Chest, abdomen &amp; pelvis (lymphoma staging or follow up):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>16</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>Abdo/ pelvis</td>
<td>20</td>
<td>14</td>
<td>-</td>
</tr>
<tr>
<td>Whole exam</td>
<td>-</td>
<td>-</td>
<td>940</td>
</tr>
</tbody>
</table>

If Diagnostic Reference Levels are consistently exceeded, please refer to local IRMER procedures.