Summary:
- All medical exposures to ionising radiation will be carried out in accordance with the Ionising Radiation (Medical Exposure) Regulations 2000, as subsequently amended (IR(ME)R).
- Departments carrying out medical exposures to ionising radiation will do so in accordance with modality specific Employer’s Procedures.
- The administration of radioactive material as part of a medical exposure will be carried out in accordance with the requirements of the Medicines (Administration of Radioactive Substances) Regulations 1978, as subsequently amended (MARS).

1 Scope

Trust-wide. This policy applies to all medical exposures to ionising radiation carried out by the Trust, including:
(a) the exposure of patients as part of their own medical diagnosis or treatment, including any exposure of an asymptomatic individual;
(b) the exposure of individuals as part of occupational health surveillance;
(c) the exposure of individuals as part of health screening programmes;
(d) the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
(e) the exposure of individuals as part of medico-legal procedures.

2 Purpose

To ensure that all medical exposures to ionising radiation are carried out in accordance with the Ionising Radiation (Medical Exposure) Regulations 2000, as subsequently amended (IRMER), and the Medicines (Administration of Radioactive Substances) Regulations 1978, as subsequently amended (MARS).
3 Definitions/Abbreviations

3.1 ARSAC
Administration of Radioactive Substances Advisory Committee

3.2 Employer’s Procedures
Procedures written to comply with the requirements of Schedule 1 of IR(ME)R.

3.3 IR(ME)R
Ionising Radiation (Medical Exposure) Regulations 2000

3.4 Medical Exposure
Any exposure to ionising radiation that falls within the scope outlined in section 1 of this policy.

3.5 MPE
Medical Physics Expert

3.6 Operator
Any person who carries out practical aspects relating to a medical exposure in accordance with local Employer’s Procedures.

3.7 Practitioner
A registered health care professional who takes responsibility for an individual medical exposure in accordance with local Employer’s Procedures.

3.8 Referrer
A registered health care professional who refers an individual for a medical exposure in accordance with local Employer’s Procedures.

3.9 Research Exposures
Any exposure required by a research protocol following initial consent from the participant, including an exposure which would otherwise be part of routine clinical care.
4 Responsibilities

4.1 Referrers / Practitioners / Operators

Referrers, Practitioners and Operators are responsible for:

- Complying with specific requirements as detailed in this policy and in modality specific Employer's Procedures.

4.2 Administration of Radioactive Substances Advisory Committee (ARSAC) Certificate Holders

ARSAC Certificate Holders are responsible for:

- Ensuring that they only take responsibility for carrying out procedures listed within their certificates.
- In conjunction with the Principle Investigator, ensuring that the number of study participants does not exceed that stated in the initial application for a Research ARSAC certificate.
- Applying for renewals to certificates prior to the expiry of the old certificates.

4.3 Imaging Services Manager (ISM) and Service Managers

The Imaging Services Manager is responsible for:

- maintaining an inventory of radiation equipment within their area.
- ensuring that modality specific Employer’s Procedures are complied with by staff in their areas.
- ensuring that an incident form is completed for any incident or ‘near miss’ relating to medical exposures to ionising radiation and that an investigation is carried out in accordance with the Trust’s incident reporting and investigation policy. This includes, but is not limited to, the investigation of exposures much greater than intended, as described in section 5.8.
- maintaining an up-to-date list of ARSAC certificate holders within the service, and keeping copies of current certificates.
- ensuring that ARSAC certificate holders apply for renewals within appropriate timescales.
- appointing sufficient numbers of suitably qualified and trained Medical Physics Experts for their areas of work;
- ensuring sufficient staff hold ARSAC certificates for all clinical and research exposures within their areas of work.

Individual Service Managers are responsible for:

- reviewing and maintaining modality specific Employer’s Procedures relevant to their areas of work.
- ensuring that all staff within their areas are appropriately trained for their role in relation to medical exposures to ionising radiation and maintaining records of this training.
ensuring that an incident form is completed for any incident or ‘near miss’ relating to medical exposures to ionising radiation and that an investigation is carried out in accordance with the Trust’s incident reporting and investigation policy. This includes, but is not limited to, the investigation of exposures much greater than intended, as described in section 5.8.

4.4 **Principle Investigator for Research Studies**

Principle Investigators for research studies are responsible for:

- identifying those research exposures which require a Research ARSAC certificate. Note that research exposures which would otherwise be part of routine clinical care do not require a Research ARSAC certificate.
- ensuring that an appropriate clinician applies for a Research ARSAC certificate.
- in conjunction with the certificate holder, ensuring that the number of study participants does not exceed that stated in the initial application for a Research ARSAC certificate.

4.5 **Directorate General Managers**

Directorate General Managers are responsible for:

- ensuring that medical exposures to ionising radiation are appropriately managed within their areas;

4.6 **The Radiation Protection Committee**

The Radiation Protection Committee is responsible for:

- Ensuring processes exist to permit the Trust to comply with relevant legislation and guidance relating to medical exposures to ionising radiation;
- Developing and reviewing the Trust’s Medical Exposure to Ionising Radiation Policy (i.e. this document);
- Reviewing and approving modality specific Employer’s Procedures.
- Carrying out an annual review of ARSAC certificates held across the Trust
- Advising the Risk Management Executive Committee on issues and concerns relating to medical exposures to ionising radiation.

The full remit of this committee and its membership is outlined in the Terms of Reference of the committee, see appendix 7 of the Trust’s Ionising Radiation Safety policy.
4.7 **The Chief Executive**

The Chief Executive, as the relevant lead Executive Director, is responsible for:

- Ensuring that this policy is implemented and monitored;
- Appointing a suitable chair of the Radiation Protection Committee;

The Chief Executive has overall responsibility for all medical exposures to ionising radiation within the Trust.

5 **Compliance with IR(ME)R**

5.1 **Employer’s Procedures**

The Trust will maintain modality specific written procedures for medical exposures to ionising radiation, which as a minimum will include the Employers Procedures specified in IRMER Schedule 1. Distinct sets of Employers Procedures will be maintained for the following modalities:

1. Diagnostic X-Ray (including CT and Interventional Imaging)
2. Breast Imaging
3. Nuclear Medicine

Service Managers will ensure that these procedures are brought to the attention of new staff as part of the local induction process and will ensure that audits of compliance with these procedures are conducted on an annual basis. Following substantial update/amendment, staff affected by the procedures will be asked to re-read these and sign to confirm that they have done so.

5.2 **Written Protocols**

Within each of the modalities identified above, departments will establish and maintain written protocols for every type of standard medical exposure.

5.3 **Referral Criteria**

Modality specific referral criteria for medical exposures will be established and published as part of the Employer’s Procedures identified in 5.1. These criteria will be made available to Referrers, with relevant dose information, through published local departmental information (which may be in hard copy or electronic format) and through links to national guidelines.

5.4 **Quality Assurance of Procedures**

The Employer’s Procedures identified in 5.1 will be formally reviewed and updated on a two-yearly basis (or as required) by managers in each modality, in consultation with staff from the Radiation Protection Service.

Following this review, updated procedures will be submitted to the Trust Radiation Protection Committee for review and approval. The Radiation Protection Committee
Protection Committee will ensure that any changes proposed do not adversely impact on patient safety or Trust compliance with IRMER. The Radiation Protection Committee will also ensure, wherever possible, that consistency is maintained between the different sets of modality specific procedures.

The Written Protocols identified in 5.2 will be formally reviewed and updated on a 2-yearly basis, by local staff within each modality. Final approval of the reviewed protocols will be made at a departmental level, and will be described in the modality specific procedures.

The Justification Guidelines referred to in 5.9 will be formally reviewed, updated and approved on a 2-yearly basis by the relevant Practitioner.

5.5 Diagnostic Reference Levels

Diagnostic Reference Levels (DRLs) will be established by the Trust for relevant medical exposures.

For x-ray examinations, recommended Trust DRLs will be drawn up and reviewed by the Radiation Protection Service, in conjunction with the local department, as part of an ongoing programme of dose audit within the Trust.

For standard Nuclear Medicine exposures, recommended Trust DRLs will be established by the local department, at a level which is at or below DRLs specified by ARSAC.

Recommended Trust DRLs will be presented to the Radiation Protection Committee for approval/re-approval on an annual basis.

Procedures for the use of established DRLs will be documented in the modality specific Employer’s Procedures. These procedures will document the process for undertaking reviews and corrective action when DRLs are consistently exceeded.

5.6 Research Exposures

Research exposures will only be carried out within the Trust following:

a) Approval by an ethics committee; and
b) Site-specific approval of the research by relevant Practitioners and Medical Physics Experts within the East Anglian Regional Radiation Protection Service.

As part of the local approval by a Medical Physics Expert, a dose constraint will be specified for any exposure where no direct medical benefit is expected for the individual.

All research exposures will follow additional research requirements outlined in the modality specific Employers Procedures.
5.7 Training

Service managers will ensure that all practitioners and operators within their areas have been appropriately trained for their roles, taking into account the requirements specified in Schedule 2 of IR(ME)R. Service managers will also ensure that staff undertake relevant continuing education and training after qualification.

Service managers will maintain training records for all Practitioners and Operators within their areas, showing the nature and dates of training relevant to each individual’s role as Practitioner and/or Operator.

5.8 Exposures Much Greater Than Intended

If any member of staff has cause to believe that a medical exposure may have occurred in which a person received an exposure greater than intended, this should be reported immediately to the service manager.

The Service Manager will ensure that an incident form is completed and that an initial investigation of the incident is initiated. This investigation will include consultation with an appropriate Medical Physics Expert. The decision as to whether or not an exposure much greater than intended occurred will be made by the MPE using the following values as a guide:
### Type of examination

<table>
<thead>
<tr>
<th>Type of examination</th>
<th>Guideline multiplying factor applied to the intended dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional radiology, radiographic and fluoroscopic procedures involving contrast agents, nuclear medicine with intended dose &gt;5mSv and computed tomography examinations.</td>
<td>1.5</td>
</tr>
<tr>
<td>Mammography, nuclear medicine with intended E≤5mSv but &gt;0.5mSv, and all other radiographic examinations not referred to elsewhere in this table</td>
<td>10</td>
</tr>
<tr>
<td>Radiography of extremities, skull, dentition, shoulder, chest, elbow, knee and nuclear medicine with intended E≤0.5mSv..</td>
<td>20</td>
</tr>
</tbody>
</table>

Unless it is shown that an exposure much greater than intended did not occur, the Imaging Services Manager or his / her deputy will report the incident:
- To the Health and Safety Executive, for incidents due to radiation equipment failure or defect.
- To the Care Quality Commission, for all other incidents.

For all externally reported incidents, the Imaging Services Manager or his / her deputy will instigate a detailed investigation of the incident using the Trust’s Incident Reporting system, and will report back to the CQC/HSE as required.

Specific examples of Exposures Much Greater than Intended, and subsequent actions, will be found in appendix 2.

### 5.9 Justification

All medical exposures carried out within the Trust must be justified by a Practitioner. There must be a record of that justification (i.e. the authorisation of that procedure). This authorisation will be recorded by the Practitioner in person, or by an Operator following Justification Guidelines issued by the Practitioner. The use of such Justification Guidelines will be described in the modality specific Employers Procedures.

### 5.10 Optimisation

Except in radiotherapy, the Practitioner and Operator for each medical exposure will ensure, to the extent of their respective involvement that doses arising from the exposure are kept as low as reasonably practicable, consistent with the intended purpose.

Optimisation relies heavily on the professional competence and skill of persons acting under the modality specific Employers Procedures, and their adherence to them. Compliance with optimisation requirements is also evidenced by:
• The Operator selecting equipment and methods appropriate for keeping medical exposures ALARP.
• The involvement of the MPE in medical exposures, as appropriate.
• Compliance with routine equipment quality assurance programs in place within each modality.
• Periodic performance testing by the MPE or other scientific/technical staff, against national recommended standards.

5.11 Clinical Evaluation

Modality specific Employers Procedures will describe the carrying out and recording of the evaluation of each medical exposure, including where appropriate, factors relevant to patient dose. As part of the auditing described in section 5.1, Service Managers will ensure that an audit of the recording of the clinical evaluation of exposures is carried out in their area.

5.12 Clinical Audit

Modality specific Employers Procedures will describe local arrangements for the carrying out of clinical audits relating to the appropriate use of Medical Exposures within the modality. This clinical audit is distinct from the audits of compliance with modality specific Employers Procedures, as described in section 5.1.

5.13 Medical Physics Expert Advice

Divisional Directors, or equivalent, will ensure that the Trust appoints suitable numbers of Medical Physics Experts. Service Managers will ensure that systems are in place to appropriately involve MPEs in all types of medical exposure.

5.14 Equipment Inventory

Service Managers will draw up and maintain an inventory of radiation related equipment within their areas, which for each piece of equipment will include:
(a) name of manufacturer,
(b) model number,
(c) serial number or other unique identifier,
(d) year of manufacture, and
(e) year of installation.

Service Managers will ensure that the amount of radiation related equipment within their area is limited to that necessary for the work being carried out.

6 Compliance with MARS

Compliance with MARS is achieved through the process for the management of ARSAC certificates, as shown in Appendix 1.
7 Monitoring compliance with and the effectiveness of this document

The compliance with and effectiveness of this document will be monitored through:

- Audits, carried out by Service Managers, of compliance with Employers Procedures, as detailed in section 5.1.
- Independent audit by the Radiation Protection Service on a two-yearly basis.

The results of this monitoring will be reviewed by the Radiation Protection Committee who will ensure that appropriate action is taken to rectify any shortfalls identified.

8 References

1. Ionising Radiation (Medical Exposure) Regulations 2000 (as subsequently amended)
2. Medicines (Administration of Radioactive Substances) Regulations 1978 (as subsequently amended)

9 Associated documents

1. Incident Reporting and Investigation Policy
2. Modality Specific Employer’s Procedures

Document management

<table>
<thead>
<tr>
<th>Author(s):</th>
<th>Nigel J. Beeton, Imaging Services Manager. Document based on that used at CUHFT: Stuart Yates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee responsible for monitoring</td>
<td>Radiation Protection Committee</td>
</tr>
<tr>
<td>Other contributors:</td>
<td>Stuart Yates (on behalf of RPA): Radiation Protection Group</td>
</tr>
<tr>
<td>Approvals and endorsements:</td>
<td>Approved by Radiation Protection Committee 25th November 2014. Reviewed by Radiation Protection Group Jan 2017</td>
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<td>Consultation:</td>
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<td>Issue no:</td>
<td>1.2</td>
</tr>
<tr>
<td>File name:</td>
<td>Medical Exposures to Ionising Radiation Policy PP(17)308</td>
</tr>
<tr>
<td>Supercedes:</td>
<td>V 1.1</td>
</tr>
<tr>
<td>Equality Assessed</td>
<td>This policy has been screened to determine equality relevance. This policy is considered to have little or no equality relevance.</td>
</tr>
<tr>
<td>Implementation:</td>
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</tr>
<tr>
<td>Monitoring: (give brief details how this will be done)</td>
<td>Via Radiation Protection Group obo RP Committee. RPC reports to Clinical Safety Executive Committee</td>
</tr>
<tr>
<td>Other relevant policies/documents &amp; references:</td>
<td>Employers Procedures; Non Medical Referrers.</td>
</tr>
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</table>
Appendix 1: Management of ARSAC Certificates in the Trust

ARSAC (Administration of Radioactive Substances Advisory Committee) licences are legally required before radioactive substances are administered for diagnostic, therapeutic, or research purposes. This is to ensure that any such processes are overseen by a competent person.

Currently ARSAC licences are held for the activities of the radioisotope imaging unit (Nuclear Medicine). New licences will be required for any newly planned procedures involving the administration of isotopes, and the person supervising the procedure will need to be able to demonstrate their competence to do so to the MPE in the first instance, and then to the ARSAC committee.

The Imaging Services Manager should be contacted in the first instance for advice on how to proceed.
Appendix 2 - Suspected Exposure Higher than Intended.

See section 5.8 above.

**Informing Patients:** In any case involving abnormally high exposure to the patient, P.A.L.S. must be contacted and the patient informed of the error. Investigations, dose reports, and risk assessments must be transparent to the patient but it is important that the PALS team are involved to see that the patient is properly supported through this experience, which is likely to be frightening and challenging for them.

**Incidents involving over-exposure or potential over-exposure at any level.**

In order to obtain optimum imaging, a certain ‘margin for error’ must be maintained to allow, for example, repeat views to be undertaken. Part of the duty of Senior radiographic staff, and particularly those responsible for reviewing rejected images as part of the QA programme, is to see that repeat imaging is monitored and that repeat images are themselves justified in terms of the benefit to the patient arising from improved imaging. Therefore a ‘repeat’ x-ray view is not an ‘incident’ in the context of this document.

Nevertheless some incidents can and do occur which result in unintended additional exposure to patients or to staff.

It is both important in its own right, and a requirement of legislation, that any incident involving a higher exposure than intended is properly investigated and actions taken to minimise the risk of a recurrence.

Any incident form involving radiation exposure, great or small, must be copied to the main x-ray radiation protection supervisor(s), who will keep a log of incidents and report to the annual radiation protection committee.

Initial investigations will be carried out by the relevant radiation protection supervisor and will be given a risk rating, using the evaluation protocol provided by the EARRPS, and if necessary reported to the RPA. The RPA will be sent a quarterly list of all radiation incidents to review and ensure that the correct process was followed.

Table A2.1 below illustrates some possible scenarios and the actions that should follow, over and above those already described:
<table>
<thead>
<tr>
<th>Incident</th>
<th>Action</th>
<th>Investigated by:</th>
<th>Time limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over exposure caused by equipment malfunction.</td>
<td>For any exposure greater than intended: Equipment taken out of use. Fault log and handover form completed. Unit repaired. QA carried out in accordance with recommendations from EARRPS. Repair documented using handover form. Patient advised of error, GP informed, patient and GP to be copied in to physics dose report.</td>
<td>Radiology Technical Officer +/- external repair staff. RPA must be consulted and will advise on any requirement for reporting to HSE.</td>
<td>Must be completed before unit returns to patient use.</td>
</tr>
<tr>
<td>Radioisotope spill</td>
<td>Follow radioisotope spill procedure.</td>
<td>Senior Nuclear Medicine Radiographer on duty. RPA must be informed of any significant spill, and will advise on any requirement for reporting to HSE.</td>
<td>Immediate, 2 working days at most</td>
</tr>
<tr>
<td>Suspected or known overdose of radioisotope, or wrong radioisotope given.</td>
<td>Scan should be attempted if clinically and radiologically acceptable. An error of +10% in individual dose administration is considered within normal limits. For repetition of a tissued dose - see below. A record is made on CRIS system and a Trust Incident form is completed.</td>
<td>Inform Medical Physics Expert. (MPE) who will advise on any requirement for reporting to CQC.</td>
<td>Immediate, 2 working days at most</td>
</tr>
<tr>
<td>Radioisotope tissued.</td>
<td>Patient given advice on managing the haematoma. If scan can still be completed, no further action. If scan has to be repeated, this does not constitute an exposure ‘much greater than intended, and does not require reporting to the CQC. Complete an incident form, coded green.</td>
<td>Senior Nuclear Medicine Radiographer on duty.</td>
<td>Immediate</td>
</tr>
<tr>
<td>Incorrect body part imaged due to inaccurate information on referral</td>
<td>Incident form completed, to include identity of operator. Imaging services manager writes to referrer, copy to consultant, (or Clinical Director), GP (or Senior Partner) advising of radiological and governance risks arising from this error. Investigating officer carefully considers any such risks that have arisen and takes documented action to mitigate them.</td>
<td>Imaging Services Manager or Deputy ISM Inform MPE who will advise on any requirement for reporting to CQC.</td>
<td>Within 5 working days.</td>
</tr>
<tr>
<td>Repeated referrer or operator error.</td>
<td>If a single operator or referrer makes three or more such errors in a period of less than 12 months, then they will be investigated by an external Superintendent Radiographer who will implement the Trust's Capability Policy if appropriate.</td>
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<td></td>
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</tbody>
</table>

Table A2.1 Actions to be taken in various scenarios involving over exposure to ionising radiation.