Trust Standard Operating Procedure

Plymouth Hospitals NHS Trust

Cooperation of Employers under the Ionising Radiations Regulations 1999 and the Ionising Radiation (Medical Exposure) Regulations 2000

Issue Date	Review Date	Version
August 2017	August 2019	1

Purpose

This procedure defines the process for ensuring cooperation between employers when work involving the use of ionising radiations

Where there may be an impact on exposure of individuals working between the two employers. This ensures compliance with the Ionising Radiations Regulations 1999 (IRR99).

Where medical exposures are provided in cooperation by the two employers. This ensure compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER)

Who should read this document?

Managers of staff working with ionising radiations, staff who work with ionising radiations.
Managers responsible for Medical Exposures of Patients
Contract managers.

Key Messages

Staff Safety
This procedure reflects the legal requirements of the Ionising Radiations Regulations 1999 and the associated Approved Code of Practice (ACOP). Adherence to this procedure will ensure compliance with these regulations with regard to cooperation between employers.
Patient Safety
This procedure ensure arrangements for medical exposures of patients are safe and comply with the requirements of the Ionising Radiation (Medical Exposure) Regulations when aspects of delivery are provided by two employers.

Core accountabilities	
Owner	Clinical and Radiation Physics
Review	Radiation Protection Committee
Ratification	Radiation Protection Committee
Dissemination	Trust Document Controller
Compliance	Radiation Protection Committee

Links to other policies and procedures

Radiation Safety Policy and Procedures

Version History

1	August 2017	Approved by Radiation Safety Committee

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to)

age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents on StaffNET. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Standard Operating Procedure (SOP)

1 Introduction

The Trust uses ionising radiations from X-ray and radiotherapy equipment and radioactive substances. It does so in order to benefit patients directly through diagnostic X-ray tests, Nuclear Medicine and Radiotherapy Services.

This procedure considers necessary arrangement for safe uses of ionising radiations when

- work with ionising radiation undertaken by one employer is likely to give rise to the exposure to ionising radiation of the employee of another employer.
- Medical exposures on Trust patients are carried out by a third party

2 Definitions

The term “ionising radiation” includes the radiation from external X-ray and electron beam generating equipment as well as radiopharmaceuticals and other sealed or unsealed ionising radiation sources.

- A “Radiation Protection Advisor” (RPA) is defined by IRR99 as an individual who meets the criteria of competence specified by the health and safety executive, and holds a certificate of competence issued by a body approved by the Health & Safety Executive.
- “Worker” is a person who as part of their duties is required to work with or in areas where ionising radiations is used,
- “Classified Person” is a person designated as such pursuant to regulation 20(1) of IRR99.
- “Outside Worker” means a classified person who carries out services in the controlled area of any employer other than their own.
- “Medical Exposure” is as defined by the Ionising Radiation (Medical Exposure) Regulations 2000 and amendments

3 Regulatory Background

The purpose of this procedure is to ensure that when , in its use of ionising radiation and the associated exposure of its patients and employees, the Trust is compliant with IRR99 and IR(ME)R 2000.

4 Key Duties

All duties should be completed with sufficient time to allow for appropriate procedure sot be put in place.

	IRR99	IRMER
Trust	Ensure arrangements are in place for cooperation of employers whenever work with ionising radiation by one employer may give rise to the exposure to ionising radiations of another employer. Examples include Trust staff undertaking secondary employment for another employer. Third party undertaking work in Trust Controlled Areas Cooperate with Third party employer in ensuring arrangements are in place, sharing of relevant information and provide assurance regarding compliance	Ensure clarity around who acts as employer under IRMER. Where the Trust outsources services the Trust remains responsible for compliance with IRMER Ensure arrangements in place for compliance with IRMER Approve any IRMER procedures implemented by the third party
Third Party Employer	Cooperate with Trust in ensuring arrangements are in place, sharing of relevant information and provide assurance regarding compliance	Cooperate with Trust in ensuring arrangements are in place, sharing of relevant information and provide assurance regarding compliance Agree to reasonable requests from the Trust to modify any existing IRMER procedures
Contract Managers	Ensure consideration is given to statutory requirements for cooperation under IRR99 Reg. 15 and MHSRW when implementing contracts with third parties	Ensure consideration is given to statutory requirements for compliance with IRMER when implementing contracts with third parties
Trust Staff	Declare any secondary employment which involves working with ionising radiations	Comply with agreed written procedures including agreed variances from 'normal' practice

Classified Person (IRR99)	Only work in a controlled area when authorised to do so. If a health review has lapsed by more than 1 month controlled area entry is not permitted. Inform their direct employer if they will be working in another employer's controlled area as an Outside Worker	
Line Manager	Ensure staff are made aware of their responsibilities with regard to IRR99 compliance	Ensure all duty holders comply with the written procedures
Duty Holder (IRMER)		Comply with all written procedures

5 Procedure to Follow

Work with Ionising Radiation involving Another Employer (Staff Safety)

Whenever any work is conducted involving Trust employees who are required to undertake work involving exposure to ionising radiations on the premises of another organisation there must be consideration of arrangements in place to ensure the safety of individuals and compliance with IRR99.

Where the Trust engages with another employer and Trust employees are required to undertake work in Controlled areas of another employer, formal arrangements must be implemented at the contractual stage.

Contracts managers and Line Managers must ensure formal arrangements are implemented with reference to Appendix A of this document

Adoption of PHT arrangements may be acceptable if formally agreed by each party. The Third party employer must formally adopt any such processes. All relevant documentation must be provided prior to commencement of any work

In all such circumstances the Trust Radiation Protection Adviser must be consulted.

When a classified person enters a controlled area of another employer they are termed an 'Outside Worker'. To enable sufficient cooperation between employers, direct employers should issue a Radiation Passbook to persons working as Outside Workers. This enables employers to identify that the classified person has been subject to sufficient medical surveillance, any restrictions that apply and their dose record to ensure legal dose limits are not exceeded.

This applies both to classified workers employed by the Trust working for another employer and classified workers employed by another employer working within the Trust

Classified employees are required to inform their direct employer prior to working in another employer's controlled area and to inform their indirect employer that they are a classified person.

Managing outside Workers in the Trust's Controlled Areas

External contractors may require access to the Trust's controlled area(s). Where these external contractors are classified persons they are deemed Outside Workers and the Trust must ensure the following prior to permitting entry:

- The classified person has been certified medically fit by an appointed doctor within the preceding 13 months
- Identification of any work restrictions resulting from medical surveillance
- An up to date dose record has been provided. This assists in preventing the exceedance of dose limits by classified workers conducting work as outside workers

Managing Trust Classified Workers

This is covered in the separate Trust Procedure 1006 "Management of Classified Persons under the Ionising Radiations Regulations 1999"

6 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of three years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the radiation protection committee and ratified by the Trust's Radiation Protection Advisors.

Non-significant amendments to this document may be made, under delegated authority from the director or senior manager, by the nominated author. These must be ratified by the director or senior manager and should be reported, retrospectively, to the group or committee.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes

7 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the director or senior manager and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

8 Monitoring and Assurance

Adherence to this procedure will be monitored through the Radiation Safety Committee

9 Reference Material

- Ionising Radiations Regulations 1999 (IRR99) and Approved Code of Practice (ACOP) L121
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)
- General Guidance for Appointed Doctors – Health and Safety Executive

Appendix Appendix XX

It is the responsibility of the contracts manager / service line manager to ensure arrangements for compliance are in place for any new Trust service. The service line manager is reposnsible for ensuring all relevant staff are aware of the requirements, trained as appropriate, and adhere to relevant policies and procedures.

It is the responsibility of the service line manager to ensure arrangements for compliance are in place for any of their staff working for other employers, or for Classified Workers, in another employers Controlled Areas – see Trust Procedure 1006

These should be detailed on the schedule below which should be included within the contractual agreements along with relevant documentation

Adoption of PHT arrangements may be acceptable if formally agreed by each party. The Third party employer must formally adopt any such processes. All relevant documentation must be provided prior to commencement of any work The checklist must be completed as part of the contractual processes and prior to any work with Ionising Radiations

	Third party proposed arrangements (description)	Documentation reference	Provided
Third Party Employer			
Description of Work			
Location of Work Planned commencement and duration			

Notification (Regulation 5)			
Prior Risk Assessment (Regulation 7) • To be performed by the third party employer and approved by the Trust's RPAs in so far as it impacts on Trust employees and the public • It is expected that such risk assessments will be suitable and sufficient under the regulations. • All relevant dose constraints to be specified			
Designated Areas (Regulation 16) • Plan showing all controlled and supervised areas			
Information, Instruction and Training (Regulation 14) • Are training records for all staff available? • Additional training required			

Local Rules (Regulation 17) • Note: it is not necessarily appropriate to state that staff will operate under Trust Local Rules, even if work is to take place on Trust premises. • Local Rules must be approved by the Trust RPAs insofar as they impact on Trust employees and the public			
Contingency Arrangements (Regulation 12) • Details must be given of all contingency arrangements, particularly where these may impact upon Trust staff and/or equipment.			
Additional Requirements for entry to Designated Areas (Controlled or Supervised) (Regulation 18) • Area Demarcation • Signage • Control of Access • Dosimetry			

Radiation Protection Supervisor (Regulation 17) • The 3PE will be expected to appoint their own RPS. Where work takes place on Trust premises, it is not appropriate to assume that the Trust RPS will act for the 3PE. • Appointment • Training • Location (on/off site)			
Radiation Protection Adviser (Regulation 13) • Provision of an RPA is the responsibility of the 3PE. Indicate if Trust staff may be asked to take on this role. It cannot be assumed that a Trust RPA will act for the 3PE. • Provide details (name, contact) • Appointed			
Provision and use of Personal Protective Equipment (Regulation 9) • Where work is to take place on Trust premises, 3PE should provide their own PPE. Specify if this is not the case. • List of approved PPE			

Maintenance & testing of Personal Protective Equipment (Regulation 10) • QA Programmes • Records			
Maintenance & testing of engineering controls (Regulation 10) • QA Programmes • Records			
Dosimetry for non-classified workers (Regulation 18) • Are there circumstances in which staff could work for both the Trust and the 3PE? If so, details must be provided of how personal monitoring will be performed and how the results will be communicated between employers. • Are the doses likely to be received by Trust staff while working for the 3PE likely to be of a magnitude such that, in conjunction with the doses received while working for the Trust, there may be a need to classify the employee?			

Classified Workers (Regulations 20-26) • Will any of the third party employer's workers be classified? If so are there any circumstances under which they could enter a controlled area of the Trust? • Are there any circumstances whereby Trust controlled workers could be required to enter a controlled area of the 3PE			
Restriction of Exposure (Regulation 8)			
Equipment used for Medical Exposure (Regulations 32) Maintenance Quality Assurance • Details of planned QA programmes • Details of Maintenance Contracts • Where Trust radiological equipment is to be used, it should not be assumed that Trust provision covers its use by a 3PE.			

Incident Management General process Notifications • Incident management and notification of relevant agencies is the responsibility of the 3PE. It is recognised that there will be circumstances in which this process will involve the Trust. The 3PE will be expected to co-operate fully with the Trust in these circumstances.			
All the above arrangements will be reviewed by the Trust's RPAs who will advise the Trust as to compliance with the regulations. The Trust reserves the right to request changes to the provisions based on the advice of its RPAs			
Radioactive Sources			
Are sealed radioactive sources to be used on Trust Premises ?			
Is a HASS source to be used? Regulations 27-33			
Are unsealed radioactive sources to be used on Trust premises?			
Has a suitable RWA been appointed?			

It is expected that the third party employer will be responsible for applying for any relevant EPR permits and for the production of the required documentation (radiological assessment, BAT etc.). Please indicate if there is any requirement for Trust personnel to participate in this process.			
Have any necessary security precautions been discussed with the CTSA?			
Is there any requirement for mobile sources to be on Trust premises?			
Has an appropriate means of storage and/or disposal of radioactive waste been determined?			

APPENDIX B : IONSING RADIATION (MEDICAL EXPOSURE) REGULATIONS

It is the responsibility of the contracts manager / service line manager to ensure arrangements for compliance are in place

These should be detailed on the schedule below which should be included within the contractual agreements along with relevant documentation

Adoption of PHT arrangements may be acceptable if formally agreed by each party. The Third party employer must formally adopt any such processes. All relevant documentation must be provided prior to commencement of any work. The checklist must be completed as part of the contractual processes and prior to any work involving Medical Exposure of Patients

	Third party proposed arrangements (description)	Documentation reference	Provided
Third Party Employer			
Description of Work			
Location of Work Planned commencement and duration			
Who Acts as Employer ? 'the organisation on whose behalf the medical exposure is carried out', that is, the organisation that has the contract with the patient, or the company/body requesting the exposure, or who has responsibility for providing the medical exposure. Where a trust has a service level agreement with an independent provider to undertake any ionising radiation work,			

the trust would be the 'employer' as this would fall within 'engages others to carry out' [CQC 2009]			
Procedures to identify correctly the individual to be exposed to ionising radiation			
Procedures to identify individuals entitled to act as referrer or practitioner or operator			
Referral Criteria			
Procedures for Justification and Authorisation Including urgency of exam			
Procedures to be observed in the case of medico-legal exposures			
Procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding			
Procedures to ensure that quality assurance programmes exist and are followed			
Procedures for the assessment of patient dose and administered activity			
Procedures for the use of			

diagnostic reference levels			
Procedures for Research Exposures			
Procedures for giving of information and written instructions as referred to in regulation 7(5)			
procedures for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose Procedure for Alerts			
procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable			
Procedures for Staff Training and Training Records (including provision of copies of training records) Qualification / Experience requirements			
Procedures for involvement of Medical Physics Expert including the appointment of an MPE – it cannot be assumed that a Trust MPE will assume this role			
Procedures for audit of written procedures			

Procedures for Incidents involving medical exposures			
Procedure for administration of contrast agents PGD / no PGD			
Examination Protocols / Techniques			
Procedures for Appointments Who is performing appointment booking ? What information is needed from the Trust by the provider ? What information is needed from the Provider by the Trust ? What information needs to be sent to each patient with the appointment ? Who / How is the booking to be recorded on CRIS ? Will there be a direct electronic link (e.g. HL7) between Trust and 3PE clinical systems?			
Procedures for Patient Attendance Where does the patient attend ? How / who records the attendance on CRIS ? If attend location is different to scan location			

What information needs to be sent to each patient with the appointment ? Who / How is the booking to be recorded on CRIS ? What contingencies if the patients attends the wrong location (information exchange) Arrangements for Clinical Emergencies			
Procedures for Image Exchange Process for sending images (provider) Process for receipt of images (PHT) Process for validating images received Contingency to ensure all images received before deletion from provider system			
For outsourced reporting Processes for Image Exchange (see above) Qualification / experience of provider staff Examinations / case mix Nature & Contents of Reports Receipt / validation of reports onto system			
IT Considerations Identify the systems involved, and map these			

systems to the activities to be undertaken Establish who requires access, types of access and training requirements Clarify preferred support arrangements Review policy and procedures and integration into data sharing agreement Inform Information Governance Committee of proposal and controls in place Existing systems within each partner organisation should be defined Inform procurement of any agreements in draft and gain their approval Existing network connectivity and bandwidth illustrated Outline system interfaces and connectivity to other external systems Outline of data management			