

## Trust Standard Operating Procedure

### Management of Classified Persons under the Ionising Radiations Regulations 2017

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#### Purpose

This procedure defines the process for designating, managing and terminating classification. This procedure applies to the management of employees whose role requires them to work with ionising radiation such that they require classification under the Ionising Radiations Regulations 2017 (IRR17).

#### Who should read this document?

Classified Persons, Appointed Doctor, Employer, Line Manager(s) of Classified persons and the Dosimetry Interface personnel.

#### Key Messages

This procedure reflects the legal requirements of the Ionising Radiations Regulations 2017 and the associated Approved Code of Practice (ACOP). Adherence to this procedure will ensure compliance with these regulations with regard to classified persons. Whereby classified persons are providing services in another employer's controlled or supervised area they are deemed an outside worker. Please refer to Trust SOP for Outside Workers.

Core accountabilities		
Owner	Nick Rowles	
Review	Radiation Safety Committee	
Ratification	Director of healthcare Science and Technology – Peter Wright	
Dissemination (Raising Awareness)	Radiation Safety Committee	
Compliance	Radiation Safety Committee	
Links to other policies and procedures		
Radiation Safety Policy : Standard Operating Procedure for Outside Workers		
Version History		
1	December 2015	
2	November 2016	Review & Approval by Radiation Safety Committee
3	March 2019	Review & Approval by Radiation Safety Committee
4	January 2020	Small Amendment, Review & Approval 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.  
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.

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## Standard Operating Procedure (SOP)

### Management of Classified Persons under the Ionising Radiations Regulations 2017

#### 1 Introduction

The Trust uses ionising radiations from diagnostic 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 applies to the management of employees whose role requires them to work with ionising radiation such that they require classification under the Ionising Radiations Regulations 2017 (IRR17).

#### 2 Definitions

- 1.2.1 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.
- 1.2.2 A “Radiation Protection Adviser” (RPA) is defined by IRR17 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.
- 1.2.3 The “Appointed Doctor” is defined by IRR17 as a registered medical practitioner who is for the time being appointed in writing by the Health and Safety Executive for the purposes of IRR17.
- 1.2.4 “Classified Person” is a person designated as such pursuant to regulation 21(1) of IRR17.
- 1.2.5 “Outside Worker” means a classified or non-classified person who carries out services in the controlled area of any employer other than their own. Refer to Radiation Safety Policy: SOP for Outside Workers
- 1.2.6 Carrying out services implies providing a benefit to the employer responsible for the controlled or supervised area.

#### 3 Regulatory Background

The purpose of this procedure is to ensure that, in its use of ionising radiation and the associated exposure of its employees, the Trust is compliant with IRR17.

Classified Person	<p>Be subject to medical surveillance, when required by the employer and at the cost of the employer, during normal working hours. The individual shall provide the Appointed Doctor (AD) with information regarding their health as is reasonably required.</p> <p>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.</p> <p>Inform their direct employer if they will be working in another employer's controlled area as an Outside Worker</p>
Appointed Doctor	<p>Liaise with the employer to ensure they have an understanding of the nature of the work to be done;</p> <p>Maintain adequate clinical records of the medical examinations completed;</p> <p>Provide counselling and advice to individuals regarding their work with ionising radiation;</p> <p>Undergo appropriate training and maintain up-to-date knowledge.</p>
Employer	<p>Designating workers as classified persons;</p> <p>Arranging for medical surveillance of classified persons;</p> <p>Maintaining a valid health record for each classified persons;</p> <p>Providing the AD with relevant information prior to the periodic health review;</p> <p>Permit the AD to view the workplace;</p> <p>Provide facilities for medical examinations or allow the employ to attend the AD's surgery;</p> <p>Notifying the AD of any suspected overexposures received by any of their employees arising as a result of their work;</p> <p>Co-operating with other employers as necessary.</p>
Line Manager	<p>Ensure persons in their workforce that are classified are aware of their responsibilities, receive appropriate training and comply with the requirements for classified workers.</p>

## Main step 1

### Classified Persons Designation Criteria

A Trust employee is deemed a classified person in the following circumstances:

- 1 *The employee is likely to receive an effective dose greater than 6 mSv a year, or an equivalent dose greater than 10 mSv per year to the lens of the eye or greater than 150 mSv per year for the skin or the extremities;*
- 2 *The employee is required to work with a source of ionising radiation which is capable of giving rise to a dose rate such that an effective dose greater than 20 mSv or an equivalent dose in excess of a dose limit could be received within a few minutes; or*
- 3 *The employer considers that there is the potential for exposure to ionising radiation that warrants classified person status (including the possibility of accidents etc. which are reasonably foreseeable) as a result of the work the individual is required to undertake.*

*These assessments must be made via the radiation risk assessment procedure in consultation with the Trust's RPA and must consider concurrent employment.*

*This should be reviewed annually or if the employee's duties change such that classification is no longer required. Classification will only be ceased at the end of the calendar year.*

## Main step 2

### Training

All persons involved must be given sufficient training with regard to these procedures and their associated responsibilities.

Classified persons must be trained in the following:

- appropriate wearing of personally issued dosimetry
- How to report a lost or destroyed dosimeters or incorrect dose measurement i.e. if the dosimeter wasn't being worn during an exposure causing an under or over-estimation
- the requirements for a medical review or examination

## Main step 3

### Medical Surveillance and Records

Medical examination by an Appointed Doctor (AD) is required prior to designation as a classified person in order to assess if it is suitable for the individual to perform this role.

Classified persons are subject to periodic reviews of health by an AD. The format of this review is at the discretion of the AD and need not involve a medical examination. A review must take place annually and a medical examination (face to face) at least once every 5 years. The annual review can be completed 1 month prior to and 1 month after the initial medical examination date termed the 'deemed date'. The deemed date remains as the initial medical examination date irrelevant as to when the review is completed. If there is a 13 month lapse between health reviews it is advisable that a medical examination takes place.

**If an appropriate medical assessment (screening or face-to-face as required) of the classified worker has not been completed within the previous 13 months access to controlled areas (of any employer) by the classified persons is not permitted.**

The arrangements at University Hospitals Plymouth NHS Trust (UHPT) are such that the AD will conduct a health review (B1) annually and a face to face (B2) medical examination will be completed on a 3 yearly basis unless otherwise specified by the AD.

Guidance for the AD is given in the 'Guidance for Appointed Doctors on the Ionising Radiations Regulations 2017' published by the HSE and issued to all Appointed Doctors <http://www.hse.gov.uk/pubns/ms33.pdf>. This guidance has links to clinical record and health record forms which are suggested formats provided by HSE for use by the appointed doctor.

## **Main step 4**

### **Dose Assessments and Records**

A dose assessment must be made of all significant doses received by classified persons. The dose assessment must be recorded and maintained until the individual would have reached the age of 75 years but in any event for at least 30 years. The employer is required to make suitable arrangements with an Approved Dosimetry Service (ADS) to make systematic assessments of doses by the use of suitable measurement techniques. Public Health England (PHE) ([doserecords@phe.gov.uk](mailto:doserecords@phe.gov.uk)) is the Approved Dosimetry Service (ADS) for UHPT and provides both the dose assessment and dose records service. Communication with the ADS should be made via the UHPT dosimetry service.

## **Main step 5**

### **Estimated Doses and Special Entries**

#### **Estimated Doses**

Where a dosimeter is lost, damaged, destroyed or deemed unrepresentative of the actual exposure of the individual an investigation shall be made into the circumstances of the exposure(s) of that individual. Service Lines must carry out the investigation in conjunction with the individual involved and the RPS. The dosimetry service/RPA can provide support and guidance.

Consideration to be given of the following:

- Details of the individual's work pattern in controlled and supervised areas
- Any other available appropriate measurements recorded by personal dosimetry
- Co-workers measured exposures
- Environmental monitoring results of the relevant controlled and supervised areas

The Head of Clinical Radiation Physics is responsible for ensuring that the ADS is informed of the estimated dose upon completion of the investigation.

Where it is not possible to accurately estimate the dose then the Trust's dosimetry service will instruct the ADS to enter a notional value which will be a proportion of the annual dose limit for the relevant period.

## Special Entries

If an employer deems a dose record entry as much greater or less\* than the actual exposure they must conduct an investigation and provide an adequate summary of the revised dose to the ADS who will amend the dose record. It will be recorded as a special entry and the investigation report supporting the dose record amendment must be preserved for 2 years from the date it was made.

\*Much greater or much less is defined as follows:

1. For doses recorded as  $\leq 1$  mSv, much greater or less is defined as a difference of  $\geq 1$  mSv
2. For doses recorded  $>1$  mSv, much greater or less is defined as a difference by a factor of 2 or more.
3. For doses recorded in excess of a relevant dose limit, much greater or less is defined as a difference of a factor of 1.5 or more.

Service Lines must carry out the investigation in conjunction with the RPS and liaise with the dosimetry service/RPA. Special entries are to be agreed by the RPA with the ADS prior to entry.

## Main step 6

### Outside Workers

When a classified person enters a controlled area of another employer they are termed an 'Outside Worker'. To enable sufficient cooperation between employers, the main employer should issue a Radiation Passbook to classified 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.

Classified employees are required to inform their direct employer that they are required to work as an outside worker prior to working in another employer's controlled area. They must inform the employer in control of the controlled area that they are a classified person and provide them with their up-to-date passbook.

For occasional visits/training etc. UHPT staff working as outside workers should ensure they wear their Trust issued personal dosimetry.

Where workers are required to routinely work as outside workers formal arrangements must be made between UHPT and the employer responsible for the controlled area in terms of training requirements, risk assessments and monitoring arrangements.

Where significant doses and/or inadvertent exposures may have been received the outside worker must inform their UHPT line manager to ensure an appropriate estimate of dose is recorded as soon as is practicable in cooperation with UHPT's RPA and the employer in control of the controlled area.

Classified external contractors may require access to the Trust's controlled area(s). These persons are deemed Classified 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

## **Main step 7**

### **Issuing and Updating Passbooks**

#### **Issuing Passbooks**

- Radiation Passbooks required for UHPT employees, i.e. classified persons required to work as Outside Workers, can be purchased from the Trust's ADS. Contact the Clinical and Radiation Physics department to apply for a radiation passbook.

C&RP-RP-Other-Dosimetry-56 Classified Worker Passbook Processes

#### **Updating Passbooks**

The employer of the Outside Worker should ensure that the radiation passbook is up to date in terms of the date and result of the last medical review including any restrictions, employer and dose record. Passbooks cannot be transferred between individuals but may continue to be used when a classified person changes employer.

Passbooks can only be updated by persons authorised by the ADS or the employer. In the case of UHPT, employee passbooks can only be updated by a trained member of the Clinical and Radiation Physics department unless otherwise agreed by the Head of Clinical and Radiation Physics.

C&RP-RP-Other-Dosimetry-54 Updating Classified Workers Passbook

#### **Concurrent Employment**

IRR17 Guidance states that each employer is required to identify total dose received by the classified person. The ADS must be provided with any available information regarding concurrent dose records kept by another employer.

If the employee works as an outside worker for a concurrent employer they should use the same passbook. Each employer should complete the relevant sections in the passbook and be assigned a unique reference (i.e. 1) and annotate it such that the dose records can be assigned to the appropriate employer.

#### **Termination Records**

A termination record refers to an individual ceasing to be a classified person and must be provided to the employer and employee by the ADS. The termination record is a record of their exposure as a classified worker. An employer can terminate the classification status of an employee if it is no longer deemed necessary under IRR17 and the relevant ACOP. If classification is deemed no longer necessary by the employer then termination as a classified person must be completed at the end of the calendar year, except in the following circumstances:

- the appointed doctor requests that the individual is no longer classified; or
- the individual is no longer employed in a capacity which is likely to result in a significant exposure during the remainder of the calendar year.

Termination of a classified person must be agreed with the Trust's RPA. The ADS will provide the termination record. Contact the clinical and radiation physics department to request a termination record.

## **6 Document Ratification Process**

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

The review period for this document is set as default of five 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 reviewed by the Radiation Safety Committee and ratified by the Executive Director for Health and Safety.

Non-significant amendments to this document may be made, under delegated authority from the C&RP Manager, by the nominated author. These must be ratified by the Executive Director for Health and Safety and should be reported, retrospectively, to the Radiation Safety 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 Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the C&RP 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**

The annual dose record is reported to the Radiation Safety Committee and reviewed. Service lines are required to review dose records and take action as required [Trust Procedure 425: Ionising Radiation Safety Policy: Managerial Responsibilities For Radiation Safety Procedure

If dose monitoring or health reviews and their associated records are not being conducted as instructed by this procedure the Trust's RPA must be informed to identify an action plan, if appropriate, to rectify the situation.

- Ionising Radiations Regulations 2017
- Ionising Radiations Regulations Approved Code of Practice (L121)
- Guidance for Appointed Doctors on the Ionising Radiations Regulations 2017
- Health record F2067 HSE 2018 [www.hse.gov.uk/doctors/forms.htm](http://www.hse.gov.uk/doctors/forms.htm)
- Clinical record FODMS101 HSE 2018 [www.hse.gov.uk/doctors/forms.htm](http://www.hse.gov.uk/doctors/forms.htm)
- C&RP-RP-Other-Dosimetry-56 Classified Worker Passbook Processes
- C&RP-RP-Other-Dosimetry-54 Updating Classified Workers Passbook

**Required documentation**

**Electronic processes and records**

**Specialised processes**