Purpose
To detail the processes whereby radioactive substances are controlled within UHPT

Who should read this document?
All persons involved in the use or management of radioactive substances

Key messages
Following the processes detailed in this document will ensure that the Trust complies with the requirements of relevant legislation

Core Accountabilities
Owner  Nick Rowles & Ivor Jones
Review  Radiation Safety Committee
Ratification Peter Wright - Director of Healthcare Science & Technology
Dissemination (Raising Awareness) Radiation Safety Committee
Compliance Radiation Safety Committee

Links to other policies and procedures
This is a subsidiary document of the Ionising Radiation Safety Policy (218) which contains full details of definitions, dissemination etc.

Version History
<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>March 2010</td>
<td>Approved by Radiation Safety Committee</td>
</tr>
<tr>
<td>1.2</td>
<td>December 2012</td>
<td>Approved by Radiation Safety Committee</td>
</tr>
<tr>
<td>2</td>
<td>April 2013</td>
<td>Reviewed and approved by the Radiation Protection Committee</td>
</tr>
<tr>
<td>2</td>
<td>April 2015</td>
<td>Extended by the Medical Director to August 2015</td>
</tr>
<tr>
<td>2</td>
<td>January 2016</td>
<td>Extended by Director of Corporate Business to January 2017</td>
</tr>
<tr>
<td>3</td>
<td>January 2017</td>
<td>Approved by Radiation Safety Committee</td>
</tr>
<tr>
<td>4</td>
<td>June 2018</td>
<td>Approved by Radiation Safety Committee</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Definitions</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Regulatory Background</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Key Duties</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Procedure to Follow</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Document Ratification Process</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Dissemination and Implementation</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Monitoring and Assurance</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Reference Material</td>
<td></td>
</tr>
</tbody>
</table>

**Appendices**

- Required Documentation (example)
- Electronic Processes and Records (example)
- Specialised Processes (example)
Standard Operating Procedure (SOP)

Procedure for Control of Radioactive Substances

1 Introduction

1.1. The Trust uses radioactive substances for medical diagnosis, therapy and research, both directly on patients and also indirectly (e.g. performing tests on biological samples or in testing instruments).

1.2. The possession of radioactive sources and the accumulation and disposal of radioactive waste are controlled by the Environmental Permitting Regulations 2016, through permits issued to users by the Environment Agency. The permits impose certain conditions and limitations, included amongst these are:

1.2.1. the requirement to have “a management system, organisational structure and resources sufficient to achieve compliance with the limitations and conditions” of the permits;

1.2.2. the provision for consultation with a suitable RPA and RWA;

1.2.3. the requirement for written operating procedures;

1.2.4. the requirement for adequate supervision by suitably qualified and experienced persons whose names are published in the locations for which they have responsibility;

1.2.5. Numerical limits on the maximum activities of material which may be held or disposed of.

1.3. The HASS regulations extend the requirements which may be associated with the above for sealed sources of high activity (as defined by the regulations).

1.4. The security of radioactive sources is governed both by EPR2016 and the National Counter Terrorism Security Office. In the light of this regulation, details of holdings of sealed radioactive sources are not made public.

2 Definitions

2.1 For the purposes of this procedure—

2.1.1. Radioactive substances are those substances subject to control under EPR2016 or HASS including those which are controlled by Exemption Orders.

2.1.2. The “use” of radioactive substances includes their involvement as part of any activity, the possession of radioactive sources and their storage and movement, and the accumulation and disposal of radioactive waste.
3 Regulatory Background

3.1 This procedure covers the use of radioactive substances throughout UHPT and is designed

3.1.1. To ensure that the holding of radioactive sources complies with the Security
Arrangements for Radioactive Sources document issued by the National Counter
Terrorism Security Office.

3.1.2. To support the provisions of the Trust Ionising Radiations Safety Policy in relation
to the control of radioactive substances.

3.1.3. To ensure that a procedural framework exists for the application of Best Available
Techniques to all accumulation and disposal of radioactive waste by the Trust.

3.2 The use of radioactive substances is governed by a number of pieces of legislation,
primarily

3.2.1. The Environmental Permitting Regulations 2016 (EPR2016)

3.2.2. The Ionising Radiations Regulations (2017)

3.2.3. The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R)

3.2.4. The High Activity Sealed Sources and Orphan Sources Regulations 2005

3.3 This procedure addresses issues within the remit of EPR2016 and HASS only. Other
issues are dealt with as follows.

3.3.1. The health and safety of individuals involved in the handling of radioactive
substances is subject to the Ionising Radiations Regulations 2017 (IRR17) (see
Trust Ionising Radiations Safety Policy and individual department Local Rules).

3.3.2. The administration of radioactive substances to humans is controlled by The
Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) (see Trust
Procedure for the Control of Medical Exposures).

3.3.3. The transport of radioactive substances by any means (road, rail, air, mail, courier
etc.) is subject to regulatory control. Transport includes all related processes: design,
manufacture, maintenance and repair of packaging; preparation, consigning, loading,
carriage, unloading and receipt of material; including storage in transit. No employee
may undertake any transport of radioactive material i.e. the sending of radioactive
substances (including waste) off site by any means, except in compliance with the
relevant legislation and after consultation with a Radiation Protection Adviser and
Dangerous Goods Safety Adviser (DGSA).

4 Key Duties

4.1 The responsibilities of Service Line Clinical Directors (through the Chief
Operating Officer), Service Line Group Managers and Departmental Heads are
described in Trust Procedure 425 “Managerial Responsibilities for Radiation
Safety”.

4.2 Other responsibilities are detailed below
## Radiation Protection Advisers

- Carry out reviews of new BAT cases and prior risk assessments on behalf of the RWA, as required.
- Audit departmental use of radioactive substances as part of their routine audit programme.

## Radioactive Waste Adviser

- Provide advice on
  - Achieving and maintaining an optimal level of protection of the environment and the population.
  - Checking the effectiveness of technical devices for protecting the environment and the population.
  - Acceptance into service, from the point of view of surveillance of radiation protection, of equipment and procedures for measuring and assessing, as appropriate, exposure and radioactive contamination of the environment and the population.
  - Regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.
- Ensuring that the annual statutory return on radioactive waste disposal is prepared and presented to the Environment Agency.
- Approval of BAT justifications submitted by departments for new or varied practices using radioactive substances.
- Monitoring compliance with permit limits on a regular basis.
- Submitting requests for variations to Environment Agency Permits when required.
- Undertake duties as defined within this procedure.
- Collate and hold the Trust Best Available Techniques case.
- Present an annual report on compliance with this procedure to the RSC.

### 5 Procedure to Follow

5.1 The Trust will control the use of radioactive substances by ensuring that there is in place:

#### 5.1.1. A procedure (this document) which has been authorised by senior Trust management and which details a transparent and robust framework for the control of radioactive substances within the Trust.

#### 5.1.2. A suitably qualified Radioactive Waste Advisor (RWA).

#### 5.1.3. An identified individual within the Trust who will coordinate the control of radioactive substances within the Trust. In practice, this will generally be the RWA.

#### 5.1.4. A written statement justifying each practice of holding or use of radioactive sources, or accumulation or disposal of radioactive waste.
5.1.5. One or more individuals appointed in each department using radioactive substances who has a defined scope of responsibility for the supervision of activities subject to a Permit under EPR2016. In practice, this will generally be the relevant RPS.

5.1.6. The requirement to report and investigate incidents involving radioactive substances.

5.1.7. The requirement to establish a mechanism for maintaining accurate records of holding and disposals of radioactive substances and for those records to be audited.

5.1.8. Regular audit of users’ procedures and practice by a Radiation Protection Adviser or Radioactive Waste Advisor.

5.1.9. The monitoring of compliance with the Control of Radioactive Substances Procedure by the Radiation Safety Committee.

5.1.10. A security system for the storage of radioactive substances, approved by both the EA and the CTSA.

5.2 The Trust recognises that the Permits issued by the Environment Agency relating to the use and disposal of radioactive substances relate to the Trust as a whole rather than individual departments. As such, funds for variations to these permits are funded corporately.

Protection of the Environment

Best Available Techniques

5.3 In using and disposing of radioactive substances the Trust is obliged to ensure that it applies Best Available Techniques (BAT) to minimise the impact on the environment and the public. In order to do so the Trust must justify:

5.3.1. Its decision to use a technique involving radioactivity;

5.3.2. Its choice of radionuclide and amount of radioactivity;

5.3.3. The way it is used and disposed of.

5.4 All reasonably available alternatives must be considered.

5.5 Best Available Techniques also implies adequate control.

5.6 The Trust must document the way in which it ensures that BAT is practised as well as the BAT justifications for specific practices. This Best Available Techniques Case must be available for inspection by the Environment Agency, on request.

5.7 A BAT statement must be prepared for the purchase of all new sources. This statement must specify the planned disposal route. The cost of this disposal may be capitalised at the purchase of the source.

Radiological Assessment

5.8 In addition to the BAT case, the Trust will also produce a Radiological Assessment for all discharges either deliberate e.g. as liquid waste through sewers or as potential accidental releases e.g. through fire.
5.9 This Assessment will provide worst-case estimates of doses to members of the public as a result of discharges of radioactive waste.

5.10 A copy will be sent to the Environment Agency with each variation to the permit and must be available for inspection by the Environment Agency, on request.
Department identifies requirement to use or handle RaS (including new or changed practices)

Produce BAT Case

Prior Risk Assessment

Pass to RWA

RWA to Review Compliance with Legislation and Permits

Resource implications and procedures for compliance agreed with user department

BAT case and risk assessment signed off by RWA

RWA prepares Radiological Assessment etc. and submits variation

Department appoints responsible person and prepares procedures for compliance

Variation approved

Variation conditions complied with

Work commences

Department maintains records in compliance with Permit

Trust-Wide

Ionising Radiations Safety Policy

Procedure for the Control of Radioactive Substances

Trust BAT Statement etc.
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Dissemination and Implementation</td>
<td>7.1 See Trust Policy No.218, The Ionising Radiations Safety Policy.</td>
</tr>
<tr>
<td>8</td>
<td>Monitoring and Assurance</td>
<td>8.1 See Trust Policy No.218, The Ionising Radiations Safety Policy.</td>
</tr>
</tbody>
</table>