Trust Policy

University Hospitals Plymouth NHS Trust

Ionising Radiation Safety Policy:
SOP for Incidents Involving Ionising Radiation

Issue Date	Review Date	Version
October 2019	October 2021	4

Purpose

This procedure is designed to ensure the appropriate reporting and investigation of incidents involving ionising radiations, and reporting to external bodies as required by legislation. This procedure will apply in all areas of the Trust and to all individuals employed by the Trust who act as duty holders under the regulations, including supernumerary staff, students, locum and agency staff, and to individuals holding honorary employment contracts.

Who should read this document?

All managers whose are responsible for the provision of clinical services utilising ionising radiations for patient diagnosis, intervention or treatment (including occupational screening, health screening programmes, medico-legal exposures, research exposures and exposure of asymptomatic individuals).

Key Messages

All incidents involving Ionising Radiation must be reported using the Datix system.

Line managers are responsible for the management and investigation of the incident as per Trust policy, but must ensure the appropriate involvement of the Radiation Protection Advisor (RPA), the Radioactive Waste Adviser (RWA), the Radiation Protection Supervisor (RPS), and the Medical Physics Expert (MPE).

The Trust will ensure that radiation incidents are investigated and reported in accordance with the requirements of the applicable regulations, to the appropriate authority(s) and within the specified timescale.

Where applicable, the external reporting of incidents involving radiation must be made as soon as practicable and in line with statutory requirements. It is the responsibility of the Chair of the Radiation Safety Committee (RSC) to report such incidents to the appropriate authority.

Core accountabilities	
Owner	Radiation Safety Committee
Review	Radiation Safety Committee
Ratification	Peter Wright, Director of Healthcare Science and 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

1	February 2001	Approved by Radiation Safety Committee
2	March 2013	
3	January 2017	Review & approved by Radiation Safety Committee

4	October 2019	Updated for revised reporting requirements under IRMER17

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.

Contents

1 Introduction

1.1 The Trust uses ionising radiations produced by X-ray and Radiotherapy equipment, and from radioactive substances for patient diagnosis and treatment. The Trust takes measures to minimise the exposure to staff, patients and the environment as far as possible. Where incidents do occur the Trust must report certain incidents to the appropriate authority.

2 Purpose

2.1 This procedure is designed to ensure the appropriate reporting and investigation of incidents involving ionising radiations, and reporting to external bodies as required by current UK legislation and guidance.

2.2 This procedure will apply in all areas of the Trust and to all individuals employed by the Trust who act as duty holders under the regulations, including supernumerary staff, students, locum and agency staff, and to individuals holding honorary employment contracts.

3 Definitions

3.1 For the purposes of this procedure, an incident involving ionising radiations relates to any incident where there is use of ionising radiations. This includes:

- Any incident that involves the over/under exposure or potential over/under exposure of a patient to ionising radiation – this includes any part of the process from patient referral to exposure/treatment and clinical evaluation
- Any incident that involves the accidental exposure or near miss of a member of staff, contractor, or member of the public.
- Any incident involving equipment using or producing ionising radiation e.g. calibrators in nuclear medicine, x-ray equipment etc
- Any incident involving the use or management of radioactive sources

4 Duties

4.1 Reporting of incidents follows the standard Trust process as per the relevant Trust policy and using the Datix system.

4.2 Managerial responsibilities are detailed in Trust Procedure 425: Managerial Responsibilities for Radiation Safety.

4.3 Additional, specific responsibilities are detailed below.

Radiation Protection Advisor (RPA)

- The RPA is responsible for providing advice should any of the following incidents occur, or where advice on an incident of this nature is required
- Overexposure of any member of staff or public, or contractor. In this context overexposure refers to the relevant dose limit.
- Any significant release or spill of a radioactive substance.
- Any loss of a radioactive source.

The RPA will advise the Chair of the Radiation Safety Committee regarding incidents that must be reported externally. Where radioactive sources are involved in the incident, the RPA should liaise with the Radioactive Waste Advisor (RWA) as appropriate.

Medical Physics Expert (MPE)

The Medical Physics Expert (MPE) must be involved in the investigations and analysis of events involving, or potentially involving accidental or unintended exposure to patients.

The MPE will advise the Chair of the Radiation Safety Committee regarding incidents that must be reported externally

Medical Physics Experts :
Radiotherapy Exposures – EXT 32478/31939
Diagnostic & Interventional X-ray – EXT 39669/39664/39665
Nuclear Medicine Exposures EXT 52281

If unclear contact the Head of Clinical & Radiation Physics -39669

Radioactive Waste Advisor (RWA)

The Radioactive Waste Advisor (RWA) must be involved with incidents which involve management or loss of sources and breach of Trust radioactive waste permits and impact the surrounding environment.
The RWA will advise the Chair of the Radiation Safety Committee regarding incidents that must be reported externally.

Dangerous Goods Safety Advisor (DGSA)

The Dangerous Goods Safety Advisor (DGSA) must be involved in investigating any accidents or incidents involving the safe transport of dangerous goods by road.
The DGSA will advise the Chair of the Radiation Safety Committee regarding incidents that must be reported externally.

Clinical & Radiation Physics

- Clinical & Radiation Physics is responsible for the coordination of incidents involving ionising radiation which are reportable externally.

Chair of the Radiation Safety Committee

- The Chair of the Radiation Safety Committee is responsible for reporting the incident to the appropriate authority but they may delegate this task to others, normally via Clinical & Radiation Physics, or the appropriate MPE, RPA, RWA or DGSA. Incidents should be reported to external agencies without delay.

On-Call Manager and Risk Management Team

- Serious Untoward Incidents must be immediately escalated to the On-Call Manager and Risk Management Team.

Employees

- Employees must ensure that where they observe or suspect an incident involving ionising radiation, the details of the incident are communicated to their line manager and entered onto Datix.

Incidents Involving Radiotherapy

- Incidents involving Radiotherapy must be categorised and reported in accordance with the requirements of the RCR/SoR/IPEM/NPSA report "Towards Safer Radiotherapy" (https://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf). All such incidents must be appropriately coded on the Datix system by the investigation manager.

Reporting to External Agencies

- Certain incidents must be reported to **External Agencies**. All such incidents, or where there is uncertainty should be notified to the Chair of the Radiation Safety Committee and to Clinical & Radiation Physics.

Analysis of Incidents

- Service Lines are responsible for the analysis of events involving or potentially involving accidental or unintended exposures to patients.

- The Radiation Safety Committee will undertake appropriate review and analysis of all incidents involving ionising radiations

5 Key Elements (determined from guidance, templates, exemplars etc)

Method of Reporting

All incidents should be reported as summarised in the flow chart table below.

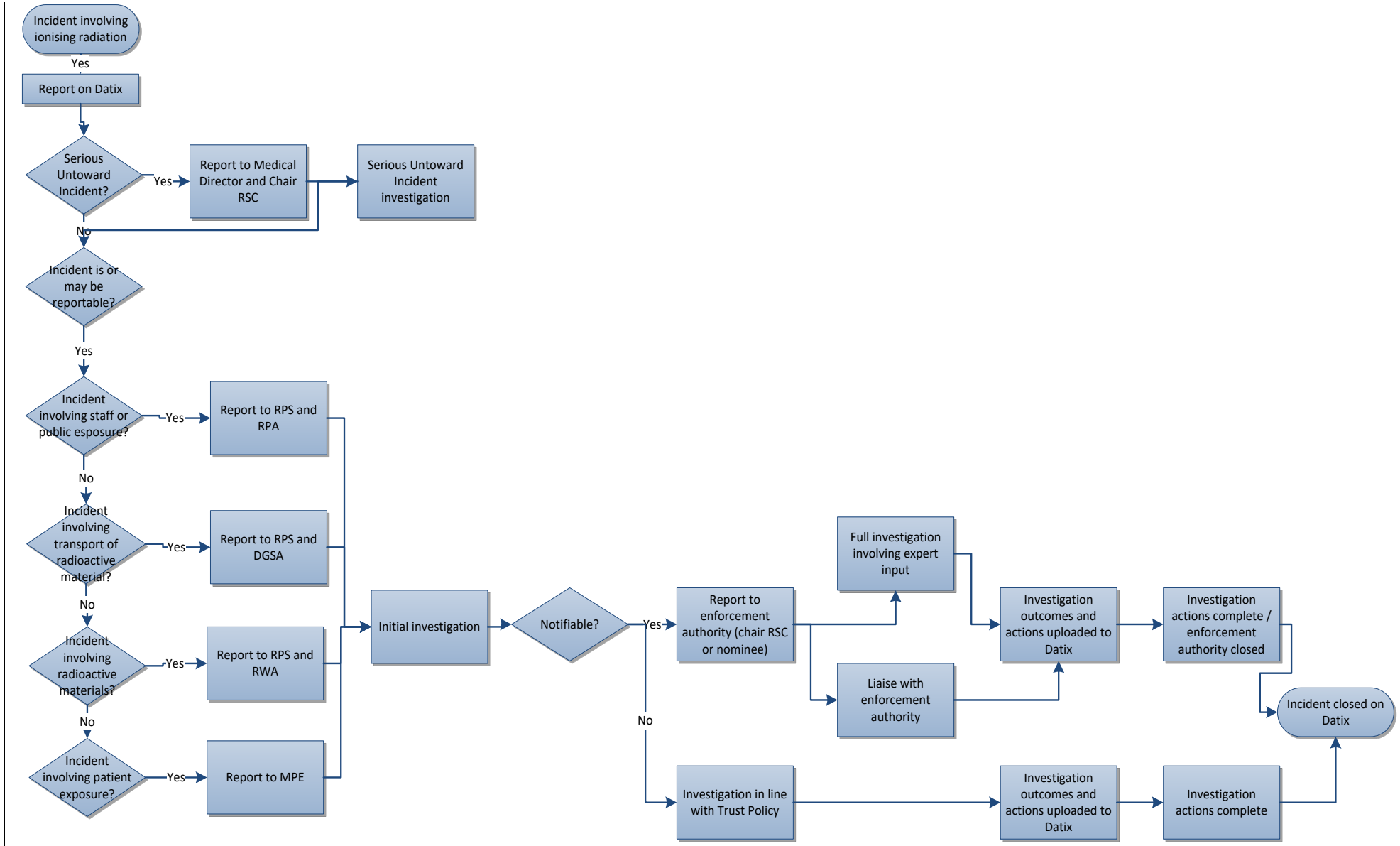
Where the initial report is made by telephone, the reporter must provide a record of the date, time and content of the phone call in writing as soon as possible and add to Datix

The Trust recognises its statutory obligation to report certain incidents involving ionising radiation to the appropriate authority.

The process for reporting incidents is summarised in the flowchart below.

When an incident has been reported in Datix, managers should identify if radiation was in use at the time, and select the appropriate box on the Datix form. This should include incidents which involve processes for medical exposures even if the exposure did not occur. The Datix field requires identification if the incidents involved ionising radiations or non-ionising radiations. If uncertain it is suggested ionising radiation is selected.

As a matter of good practice the outcome of incident investigations should be shared with the individuals involved.


Incident involving ionising radiation
Yes
Report on Datix
Serious Untoward Incident?
Yes
Report to Medical Director and Chair RSC
Serious Untoward Incident investigation
No
Incident is or may be reportable?
Yes
Incident involving staff or public esposure?
Yes
Report to RPS and RPA
No
Incident involving transport of radioactive material?
Yes
Report to RPS and DGSA
No
Incident involving radioactive materials?
Yes
Report to RPS and RWA
No
Incident involving patient exposure?
Yes
Report to MPE
Initial investigation
Notifiable?
Yes
Report to enforcement authority (chair RSC or nominee)
Full investigation involving expert input
Liaise with enforcement authority
Investigation outcomes and actions uploaded to Datix
Investigation actions complete / enforcement authority closed
Incident closed on Datix
No
Investigation in line with Trust Policy
Investigation outcomes and actions uploaded to Datix
Investigation actions complete

Reporting to External Agencies

The Care Quality Commission (CQC)

The Care Quality Commission must be notified for breach of the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R, in the case of Accidental or Unintended Exposure where the levels of radiation received are 'significantly greater' than those proportionate to the circumstances.

Guidance on accidental and unintended exposures which require notification is published by the Department of Health on the official IRMER 2017 web page (URL below):

https://www.cqc.org.uk/guidance-providers/ionising-radiation/definition-significant-accidental-or-unintended-exposures

Health and Safety Executive (HSE)

The HSE must be notified of:

- Certain occurrences with radioactive sources, depending on the activities involved:
  - IRR17 Reg. 31(1): accidental spillage or release of activity in excess of that given in column 5, Sched.7
  - IRR17 Reg. 31(3): loss or theft of a source of activity in excess of that given in column 6, Part1 of Sched.7
- An overexposure of any individual or individuals (IRR17 Reg 26 (1)), where an overexposure is defined as a dose received by a person that exceeds the dose limit for that period.
- RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013): http://www.hse.gov.uk/riddor/report.htm

The Environment Agency

The Environment Agency must be notified of

- Any loss, breakage or dispersal of any registered source.
- Any malfunction, breakdown or failure of equipment or techniques, accident or disposal which has caused, is causing or may cause significant pollution or may generate significant amounts of radioactive waste.
- Breach of any permitted limit.

The Medicines and Healthcare Regulatory Authority (MHRA)

The Medical Devices Regulations require reporting to MHRA of any incidents relating to medical equipment which led to, or might have led to, death or serious injury to patients, users and others. It is recommended such incidents also be reported to equipment manufacturers.

The Office for Nuclear Regulation (ONR):

The ONR must be notified of incidents involving the loss of (security breach), or incidents involving carriage of dangerous goods. http://www.onr.org.uk/notify-onr.htm

Timescales for Reporting Incidents

- All incidents should be reported to the relevant agency as stipulated by that authority and without delay.
- The requirements for reporting to the Environment Agency in accordance with the Environmental Permitting Regulations 2016 are specified in the relevant

permit. This may be within 24 hours for certain incidents.

- The CQC state that for incidents notified in accordance with the Ionising Radiation (Medical Exposures) Regulations 2017, they normally expect notifications should be made 'forthwith' after a preliminary investigation. The Significant Accidental and Unintended Exposures (SAUE) notification guidance June 2019 states; *employers need to make the notification no later than 2 weeks after discovering the incident*.
- There may be cases where it takes longer to establish if an incident has occurred. In such cases the investigator should liaise with the chair of RSC regarding the timing of the notification. It may be appropriate in these cases to discuss the incident informally with the CQC before reporting
- For Notifiable incidents under the Ionising Radiations Regulations 2017, HSE must be notified
  i) as soon as practicable in the case of overexposure (Regulation 26)
  ii) immediately notify for any release or spill requiring notification (Regulation 31)
  iii) notify HSE of failure of source to return to safe position through normal means (Regulation 31)
  iv) Loss of source requiring notification – immediately notify HSE (Regulation 31)
- MHRA 'Yellow card Scheme 'suggest that reports should be made as soon as possible regarding medical devices..
- ONR – report as soon as possible regarding incidents involving carriage of dangerous goods.4.8

Agency	Means of Contact
Care Quality Commission	https://www.cqc.org.uk/content/reporting-irmer-incidents
Health and Safety Executive	State that the incident is being reported under IRR17 and not RIDDOR e-mail : irrnot@hse.gsi.gov.uk **RIDDOR notification:** http://www.hse.gov.uk/riddor/report.htm
Environment Agency	0800 80 70 60 or to local named inspector e-mail: Not to be used for the initial report as it may delay the EA response Online reporting: None
MHRA	Only for incidents involving death, serious injury or serious public health concern https://www.gov.uk/report-problem-medicine-medical-device
ONR	http://www.onr.org.uk/notify-onr.htm

Duty of Candour

Clinically Significant Accidental or Unintended Exposures:

IRMER Reg. 8(1) - In the event of a 'clinically significant' unintended or accidental exposure, requires the referrer, practitioner and individual exposed or their representative to be informed and of the outcome of the analysis.

'Clinically significant'- has been locally defined as a moderate harm and above.

For incidents where there is potential harm (increased risk of life time cancer), a moderate incident is defined as a risk of 1 in 1000 – 1 in 100 (Calnan K 1996) (10.2).

A risk of 1 in 1000 equates to a nominal effective dose of 20 mSv, however age related risk factors apply (the risk to a child is greater, to an older patient less). Advice should be sought from the MPE in each circumstance.

Incidents where the severity of the incident is moderate or greater fall under the Duty of Candour as required for the Health & Social Care Act 2012.

Duty of Candour processes follow the general Trust incident management policy. The clinical service line is responsible for undertaking the Duty of Candour.

DOH Advice (10.5) states: *The regulation allows for circumstances where it is not in the best interests of the patient to be informed of such an exposure. For example, delivery of radiotherapy to a patient undergoing palliative treatment, where the effects of an unintended or accidental exposure are unlikely to become apparent in the remaining life of the individual, but being informed of the incident may have a detrimental effect on the patient's well-being. Such circumstances will be exceptional and in practice the practitioner and the referrer should be involved in this decision and the basis for the decision recorded in the patient's notes. In such cases however, it is recommended that a representative of the patient is informed wherever possible.*

Accidental and Unintended Exposures:

Joint Professional Guidance form British Institute of Radiology (BIR) (10.4) states " *In most cases where an incident has occurred and this is identified at the time an apology should be given. When patients are informed of errors and explanations of risk are given it is advisable to consider risks in broad categories…Where incidents are identified at a later date and the risk is small, consideration should be given to whether informing the patient may cause unnecessary distress."*

The requirements of this regulation are consistent with the general need to conduct clinical practice in an open and transparent environment.

The profroma letter below can be used by the relevant Service Line. Advice of the MPE should be sought.

Consideration should be given to speaking to the patient or their representative in person.

Our ref:

Date:

Private and Confidential

Address

Dear Mr/Mrs/Ms/Sir etc.

I am writing to you as the ……..for …… at University Hospitals Plymouth NHS Trust regarding an incident whereby you underwent **(*include details of incident i.e. a repeated CT scan due to an operator error*)** In turn this meant that there was further exposure to additional radiation which could have been avoided.

Firstly, I would like to express our sincere apologies that this occurred and am sorry if this caused you any additional distress. Members of our team are currently investigating the events leading up to the errors made so that we understand what happened. At the time, this error was identified and recorded as an incident and as we are required to do, the incident has been reported to the Care Quality Commission.

A detailed investigation will be carried out to ensure we identify the errors that occurred which will enable us to take appropriate measures to improve our processes to ensure such errors do not happen in the future.

Examinations involving **(*insert type of imaging involved*)** are known to increase very slightly the risk of cancer later in life. Clearly there is an additional risk because (*insert particulars of the incident*). We have evaluated the level of risk according to the additional radiation dose you received and this would be considered **(*insert PHE risk descriptor from physics dose estimate*)** as described in guidance by Public Health England.

Please accept my apologies on behalf of the Trust that your care has fallen below the standards we expect. If you would like a summary of the outcomes from our investigations or have any further questions at this time please do not hesitate to contact us by using the following details –

(Insert SL) Service Line Offices

Level (*insert level*)

Derriford Hospital

Plymouth

PL6 8DH

Telephone:

Yours Sincerely

6 Overall Responsibility for the Document

6.1 See the Ionising Radiation Safety Policy (Trust Policy 218).

7 Consultation and Ratification

7.1 See the Ionising Radiation Safety Policy (Trust Policy 218).

8 Dissemination and Implementation

8.1 See the Ionising Radiation Safety Policy (Trust Policy 218).

8.2 The Radiation Safety Committee will be responsible for agreeing the training requirements associated with the newly ratified document with the named Executive Director, updating the radiation protection training matrix and, working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Monitoring Compliance and Effectiveness

9.1 See the Ionising Radiation Safety Policy (Trust Policy 218).

10 References and Associated Documentation

10.1 See the Ionising Radiation Safety Policy (Trust Policy 218).

10.2 Cancer : science and society and the communication of risk. Calnan K. BMJ 313. 799-802 1996

10.3 Incident management Policy

10.4 A guide to understanding the implications of the Ionising Radiation (Medical Exposures) Regulations in diagnostic and interventional radiology - Ref No BFCR(15)2 2015

10.5 Guidance to the Ionising Radiation (Medical Exposures) Regulations 2017. DOH. June 18.

Dissemination Plan and Review Checklist | Appendix 1

Core Information	
Document Title	RADIATION SAFETY POLICY Procedure for Medical Exposures
Date Finalised	
Dissemination Lead	Trust Document Controller
Previous Documents	
Previous documents in use?	Trust documents, QPulse
Action to retrieve old copies.	Trust document controller, update on QPulse

Dissemination Plan

Recipient(s)	When	How	Responsibility
All Trust staff		Vital Signs	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	✓
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	✓
	Does the style & format comply?	✓
Rationale	Are reasons for development of the document stated?	✓
Development Process	Is the method described in brief?	✓
	Are people involved in the development identified?	✓
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	✓
	Is there evidence of consultation with stakeholders and users?	✓
Content	Is the objective of the document clear?	✓
	Is the target population clear and unambiguous?	✓
	Are the intended outcomes described?	✓
	Are the statements clear and unambiguous?	✓
Evidence Base	Is the type of evidence to support the document identified explicitly?	✓
	Are key references cited and in full?	✓

	Are supporting documents referenced?	✓
Approval	Does the document identify which committee/group will review it?	✓
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	✓
	Does the document identify which Executive Director will ratify it?	✓
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	✓
	Does the plan include the necessary training/support to ensure compliance?	✓
Document Control	Does the document identify where it will be held?	✓
	Have archiving arrangements for superseded documents been addressed?	✓
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	✓
	Is there a plan to review or audit compliance with the document?	✓
Review Date	Is the review date identified?	✓
	Is the frequency of review identified? If so is it acceptable?	✓
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	✓

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	
Title	
What are the aims, objectives & projected outcomes?	
Scope of the assessment	
Collecting data	
Race	
Religion	
Disability	
Sex	
Gender Identity	
Sexual Orientation	
Age	
Socio-Economic	
Human Rights	
What are the overall trends/patterns in the above data?	
Specific issues and data gaps that may need to be addressed through consultation or further research	

Involving and consulting stakeholders				
Internal involvement and consultation				
External involvement and consultation				
Impact Assessment				
Overall assessment and analysis of the evidence				
Action Plan				
Action	**Owner**	**Risks**	**Completion Date**	**Progress update**