Procedure and process for incidents involving radiation (including overexposure)

Document reference: MPQP06

An appendix to Trust Radiation Safety Policy

Mandatory for: All areas where ionising radiation is produced or used.

Date Written: 9/1/12
Date Revised: June 2017
Written and approved By: Dr. Steven Crook, Head of Medical Physics
Ratified By: N/A – Local policy
Date Approved: 2/9/2016
Next Due for Revision: September 2018
Date Policy Becomes Live: September 2016

Version No. | Updated By | Updated On | Description of Changes
---|---|---|---
1 | Steven Crook | 4/10/12 | Initial version with chart to describe involvement of Risk dept. and Radiology manager.
2 | Steven Crook | 20/9/13 | Amended for MGTI revision and 'overexposure' for non-patient groups
3 | Steven Crook | 8/9/15 | Review with minor amendments
4 | Steven Crook | 5/9/16 | Revise to Trust format and amend flowchart to incorporate DATIX risk reporting.
5 | Steven Crook | 20/6/17 | Amend to update latest IRMER/MGTI reporting guidance and web links.

Table of Contents

1.0 Introduction ................................................................. 2
2.0 Glossary ........................................................................... 2
3.0 Purpose of procedure ....................................................... 2
4.0 Responsibilities ............................................................... 3
5.0 Procedure detail .................................................................. 3
6.0 Records ............................................................................ 4
7.0 References ........................................................................ 4
1.0 Introduction

1.1 As part of the conditions for using X-rays and radioactive material, Salisbury NHSFT needs to make reports to the appropriate authorities in cases where a radiation incident has occurred or is suspected of having occurred. This is to ensure legal compliance with Ionising Radiation Regulations 1999 (IRR99, part of Health and Safety at Work legislation) and Ionising Radiation (Medical Exposure) Regulations (IRMER).

1.2 A radiation incident can arise from an accidental exposure (wrong patient, wrong side, member of staff/public exposed/overexposed) due to human error or equipment malfunction. In addition, failure of controls designed to restrict exposure to staff and the public can lead to an overexposure requiring investigation and possible action.

1.3 The care, treatment and wellbeing of any patient, involved or not, takes priority over investigation and reporting. i.e. critical staff should not be removed to undertake incident reporting until and unless patients are properly cared for.

1.4 Salisbury NHSFT has a Radiation Safety Policy (RSP) which governs the way in which the Trust complies with the legislation and advice governing radiation.

This procedure & process is additional to Salisbury NHSFT Incident reporting procedure (DATIX). Communication related to any DATIX incident should take place within the DATIX mechanism.

2.0 Glossary

ALARP  As Low As Reasonably Practicable
EA  Environment Agency
HSE  Health and Safety Executive
IRMER  Ionising Radiation (Medical Exposure) Regulations 1999
IRR99  Ionising Radiation Regulations
MPE  Medical Physics Expert
RPA  Radiation Protection Advisor
RPS  Radiation Protection Supervisor
RAW  Radioactive Waste
RSC  Radiation Safety Committee

3.0 Purpose of procedure

3.1 To ensure any incident involving radiation (X-rays, nuclear medicine and Genetics Labs) is reported to the appropriate authority or authorities within their stated time limits.

3.2 To provide guidance as to the management structure in place and persons required to be informed within Salisbury NHSFT.

3.3 To provide guidance as to the scientific and technical resources available and likely to be required.
5.0 Procedure detail

5.1 Incident involving equipment.
For an incident where there is a machine fault or malfunction and a patient or member of staff may have been irradiated a preliminary investigation shall be made. This investigation will usually involve the RPS and a Radiology Manager. The incident should be entered onto DATIX and flagged as a radiation incident.

5.2 Medical Physics will be alerted via DATIX. Unless preliminary investigation shows beyond reasonable doubt that a radiation dose ‘much greater than intended’ did not occur an estimate of any dose and whether or not it was ‘much greater than intended’ will be made. If the Medical Physicist or RPA cannot be contacted this should not prevent a preliminary report being filed with the HSE. If the incident recurs or the equipment is felt to be sub-standard then this can be reported to the MHRA.

5.3 Incident involving equipment/accident resulting in a release of radioactive material.
As soon as practicable after such an incident, Medical Physics should be contacted to determine if a breach of the Environment Agency Permit conditions has occurred or a dose “much greater than intended” has been incurred. Nuclear Medicine and the Genetics Labs have local spill procedures to manage contained contamination – Medical Physics should be involved once immediate action to contain the spill has been performed.

5.4 Incident involving a patient exposure as a result of human/procedural error.
Where a patient has received an unintended dose much greater than intended as a result of an error this is an IRMER incident. As such it should be reported to the CQC. A preliminary investigation should be conducted by the staff involved (see flowchart below) and Medical Physics contacted to provide a dose estimate. If it is determined that a dose ‘much greater than intended’ has been incurred then the investigation should be submitted ‘forthwith’ to the CQC. They would expect a report with 2 weeks of the exposure having occurred.

5.5 Incident involving a breakdown in controls designed to restrict exposure
Where an actual or suspected breakdown in exposure controls has occurred an initial investigation shall be made. This may require the immediate processing of personal dosemeters to determine the extent of any exposure to staff (worn by all operators). Unless it can be demonstrated that no breakdown occurred a more detailed investigation will be required.

5.6 Reports for all incidents
A report with the following content is suitable for an initial submission. Establish and report what happened.

**Equipment:**- identify the defect or malfunction in the radiation equipment to establish the cause(s) if possible. (include: make, model, age and manufacturer of equipment)

**IR(ME)R:**- the root cause(s) of the incident or how this is being investigated.
Whether any previous patients might have been overexposed. Is there a trend which might point to a systematic failure.
Whether the patient is being informed or the reasons why not. (Duty of Candour)

**IRR99 Controls** the extent of any exposure to staff and/or public and impact on any dose limit that applies (exceeded/not exceeded). (Reg 25, IRR99 requires that suspected overexposures are reported to HSE – refer to L1216.3 for details)

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### 4.0 Responsibilities

<table>
<thead>
<tr>
<th>EMP</th>
<th>Radiation Employer</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPS</td>
<td>Radiation Protection Supervisor</td>
</tr>
<tr>
<td>MPE</td>
<td>Medical Physics Expert</td>
</tr>
<tr>
<td>LMT</td>
<td>Local Management team (from the department organising new or changed work/equipment)</td>
</tr>
<tr>
<td>RPA</td>
<td>Radiation Protection Advisor</td>
</tr>
<tr>
<td>RMU</td>
<td>Radioactive Material User</td>
</tr>
<tr>
<td>RAD</td>
<td>Radiology Management</td>
</tr>
</tbody>
</table>

Top of Page
5.6 Continued...

**IRR99 Releases** under Reg 30 releases (including spills) over a specified level shall be notified to HSE. (for Technetium 99m, > 10 TBq. For P-32 > 100GBq - ACOP Schedule B column 4.)

Report on any remedial action decided and implemented to prevent a recurrence. Estimate the dose received by all persons involved in the incident. How the events are covered by internal governance. How the incident is being fed into risk management. The level of senior management being informed. For the more simple events this may also be the final report. The report status (preliminary/interim/final) and timescale set for any follow up actions should be indicated.

5.7 Prior to submission of the report the management involved should have the opportunity to review the content. In particular the Diagnostics DMT must be sent the report. They will alert internally (e.g. other Directorates, Risk Management, Executive Board). The intention to report externally will be noted on DATIX.

5.8 Following submission of a preliminary report the CQC/HSE may/will request further points to be addressed in a final report. This request will come back via the person who submitted the initial report and may need disseminating as in 5.6 in order for the points to be addressed. Points may be answered individually or in the form of a further report.

5.9 The CQC/HSE will inform SNHSFT when they have closed their file and this will be circulated along with their findings/statement.

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### 6.0 Records

6.1 SNHSFT Incident/Risk system – DATIX
6.2 Radiation incident report – as required

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### 7.0 References

7.1 [CQC reporting page, advice and link to online submission form](https://www.cqc.org.uk/guidance-providers/ionising-radiation/reporting-irmr-incidents)

**IRMER/CQC Guidance revised January 2017**

<table>
<thead>
<tr>
<th>Examples of unintended medical exposures that require notification</th>
<th>When to notify (what constitutes an exposure much greater than intended)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Modalities</td>
<td>All cases – regardless of dose</td>
</tr>
<tr>
<td>Wrong patient exposed</td>
<td>All cases – regardless of dose</td>
</tr>
<tr>
<td>Wrong radioactive medicinal product administered</td>
<td>All cases – regardless of dose</td>
</tr>
<tr>
<td>Unintended planning or verification exposures. Examples include wrong protocol/plan, patients placed in the imaging pathway in error.</td>
<td>All cases – regardless of dose</td>
</tr>
</tbody>
</table>
Wrong examination including incorrect body part or modality. **Excluding** diagnostic imaging laterality errors in the anatomy distal to the hip and shoulder. These incidents do not require notification but should be investigated locally.

Timing errors when an additional unintended examination is undertaken e.g. outside clinically acceptable time frame of the intended date

Where an incident involves exposure of several people to an extent that is greater than intended (but less than the guideline factors) as a result of a systematic process or clinical failure

Failure to follow procedure regarding pregnancy and breastfeeding enquiries resulting in an unintended exposure to the foetus or unintended exposure of a child through breastfeeding

Unintended foetal exposure where there was no failure to follow procedure regarding pregnancy enquiries

Any other situation where a patient has been exposed to ionising radiation, which in the judgement of the employer, is much greater than was intended for that patient

<table>
<thead>
<tr>
<th>Table 2 – Guideline factors for diagnostic and interventional procedures, including pre-treatment (planning) imaging and during treatment (verification) imaging</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnostic and Interventional exposures</strong></td>
</tr>
<tr>
<td>High dose examinations, where the intended dose is greater than 5mSv, to include interventional radiology, radiographic, and fluoroscopic procedures involving contrast agents, diagnostic nuclear medicine, PET-CT and CT examinations</td>
</tr>
<tr>
<td>All radiotherapy planning and verification imaging</td>
</tr>
<tr>
<td>Intermediate dose examinations, where the intended dose is within the range 0.5 - 5mSv, to include mammography, CT scout examinations, and all other radiographic examinations not referred to elsewhere in this table</td>
</tr>
<tr>
<td>Low dose examinations, where the intended dose is less than 0.5mSv, to include DEXA, skull, dentition, chest, in-vitro nuclear medicine</td>
</tr>
</tbody>
</table>
7.2 Guidance for exposures – ‘much greater than intended’ under HSE PM77/Reg 32 IRR99 (equipment related)

<table>
<thead>
<tr>
<th>Type of diagnostic examination</th>
<th>Guideline multiplying factor applied to 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, 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>

http://www.hse.gov.uk/pubns/guidance/pm77.pdf

7.3 Ionising radiation regulations and approved code of practice
http://www.hse.gov.uk/pubns/priced/l121.pdf

7.4 Health and Safety Executive reporting
notification_for-ionising_radiation@hse.gsi.gov.uk
Or Fax to Bristol office.
4th Floor, The Pithay
All Saints Street
Bristol
BS1 2ND
Fax: 01179 262998