ACCIDENT/INCIDENT & PATIENT SAFETY INCIDENT REPORTING POLICY
INCLUDING SERIOUS INCIDENTS REQUIRING INVESTIGATION

Summary

The Trust’s electronic procedures for reporting and investigating accidents, non clinical incidents, near misses and patient safety incidents aim to support active learning and to ensure that the positive lessons learnt from these events are embedded into the organisation’s culture and practices. Learning from incidents is an essential part of Integrated Governance and Risk Management within the Royal Marsden NHS Foundation Trust and also a requirement of the Trust Risk Management Policy.

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1. INTRODUCTION

1.1 The Department of Health document “An organisation with a memory” highlighted the importance of reporting and acting on reports of adverse health care events and potential adverse events. The document recognises that the majority of incidents could be avoided if only the lessons of experience were properly learned.

1.2 Creating a learning environment involves creating an open ‘fair blame’ culture for incident reporting. The focus for an incident investigation should not be to identify an individual who can be blamed or to search for evidence of negligence; instead the investigation should aim to identify the ‘latent conditions’ (risk factors) that resulted in the incident occurring.
1.3 The Department of Health requires the mandatory reporting of specific accidents, incidents and patient safety incidents by all healthcare organisations. All incidents classified as Serious Incidents must also be reported to the Commissioners, the Clinical Commissioning Group and Monitor.

2. POLICY STATEMENT

2.1 The Trust's procedures for reporting and investigating accidents, non clinical incidents, near misses and patient safety incidents aim to support active learning and to ensure that the positive lessons learnt from these events are embedded into the organisations culture and practices. Learning from incidents is an essential part of Integrated Governance and Risk Management within the Royal Marsden NHS Foundation Trust and also a requirement of the Trust Risk Management Policy.

2.2 All accidents, non clinical incidents, near misses and patient safety incidents, irrespective of their severity, will be recorded and reported on an incident form using the Trust's electronic incident reporting system. Other forms of reports are only used in an emergency when electronic systems are unavailable.

2.3 Where departments take part in any voluntary reporting scheme for critical incidents e.g. as operated by the Royal College of Anaesthetists, a Trust Incident Report Form must still be completed. ALL accidents, non clinical incidents, near misses and patient safety incidents must be reported onto an electronic incident form and formally investigated internally in accordance with Trust Policy.

2.4 All incidents will be risk rated according to the Trust’s accident/incident reporting policy. All serious incidents are rated as high (red) risks.

2.5 Reports from Serious Incident Investigations and formal incident investigations will be reviewed by the Trust Integrated Governance and Risk Management Committee (IGRM) and appropriate risk management action plans discussed. The Quality, Assurance and Risk Committee (QAR) will monitor the implementation of identified action plans as required.

2.6 It is recognised that fear of reprisal, blame and/or disciplinary action may deter staff from reporting an incident (or potential incident). This should not be the case. In order to further support a fair blame culture, the Trust has a Whistleblowing Policy (Policy no. 229).

2.7 Patients should be informed of all patient safety incidents using the principles of Being Open and the requirements of the Duty of Candour. The Being Open / Duty of Candour process should be followed for all incidents graded Orange and above.

2.8 The view of the Trust Board is that disciplinary action should not form part of the response to an incident investigation unless there are exceptional circumstances.
“Exceptional Circumstances” can be defined as the following occasions:-

- Deliberate failure to report an incident
- Failure to co-operate with an investigation
- Criminal action, or,
- Where it is the view of the Trust and/or professional body that the actions were so far removed from reasonable practice that any competent practitioner would have been able to predict the adverse outcome
- Repeated incidents that require investigation involving performance.

3. POLICY OBJECTIVES

3.1 In order to meet statutory duties to record and review accidents and incidents to any persons affected by its work activities, the Trust will:-

a. Maintain a standard Accident/Incident Report Form that will comply with Health and Safety Executive (HSE) and ISO9001 Non Conformance reporting standards. This is available on the Hospital Intranet.

b. Provide an electronic reporting system that can be used to generate useful data for risk management within the Trust. Currently this is a Datix system.

c. Maintain an accident/incident reporting system that will assist managers to identify, record and review risk assessment procedures within their areas of responsibility.

d. Implement standard procedures to ensure that all incidents are reviewed as part of line management responsibility and that the relevant line manager gives immediate feedback to the individual reporting the incident.

3.2 The Trust’s Accident/Incident Reporting Policy applies to all staff and all departments within the Trust.

3.3 In accordance with the requirements of the National Reporting and Learning System (NRLS) reportable incidents will be forwarded to the NRLS, Care Quality Commission (CQC) and the Clinical Commissioning Group in accordance with mandatory reporting procedures.

3.4 The Pharmacy Department will maintain records of all reported Adverse Drug Reactions (ADRs) and will report these to the Medicines Control Agency as appropriate. In accordance with the Trust’s Policy and Guidelines for Medicines Management, all ADRs should be reported to the Pharmacy Medicines Information Department.

3.5 If an incident is identified which has occurred while the patient is not under the Trust’s care it is seen to be not attributable to The Royal Marsden. The incident must still be reported on Datix. The organisation that was responsible for the care of the patient at the time of the incident will be notified and the details recorded in the appropriate section of Datix. This ensures that other organisations are aware of incidents and can put actions in place to prevent reoccurrence.
4. DEFINITIONS AND CATEGORIES

4.1 In accordance with National Patient Safety Agency standards, the Trust has adopted the following definitions for patient safety incidents:

4.1.1 Patient Safety Incident

4.1.2 A patient safety incident is any unintended or unexpected accident which could have or did lead to harm for one or more patients receiving NHS care.

Patient safety incident is an umbrella term which is used to describe a single incident or a series of incidents that occur over time. Terms such as adverse, error or mistake suggest individual causality and blame.

The main categories of patient safety incidents are:
1. Medication incident
2. Consent incident
3. Surgical incident
4. Anaesthetic incident
5. Medical device incident
6. Medical records / Clinical information. Breaches in confidentiality
7. Radiotherapy / Brachytherapy and systemic isotope incidents
8. Diagnostic radiology
9. Pathology

4.1.3 Types of patient safety incidents
- Incidents that staff are involved in
- Incidents that staff may have witnessed
- Incidents that caused no harm or minimal harm
- Incidents with more serious outcomes
- Prevented patient safety incidents (also known as near misses)

4.2 Non Patient Safety Incident Definitions

4.2.1 Accident

“An unplanned undesired non-clinical event which could have or did lead to the injury or death of any person affected by the Trust’s activities”.

This definition therefore includes injuries to staff, visitors and contractors. The definition also applies to any incident involving a patient that is not directly related to their clinical care for example, a patient fall would be included as an accident.

4.2.2 Non-Clinical Incident

Examples of non-clinical incidents reportable under this policy are:
1) Accident to member of staff, patient, visitor or other person
2) Security incident
3) Violence, aggression
4) Ionising radiation incident (non-clinical)
5) Equipment (non-medical) incident
6) Environmental incident, e.g. chemical spillage, flood, fire, waste disposal incident
7) Food safety incident
8) Information and Technology incident

4.2.3 Non Clinical Prevented Incident
A situation in which an event or omission, or a sequence of events or omissions fails to develop further, whether or not as the result of compensating action, thus preventing harm/injury.

4.2.4 Non Attributable Incident
A patient safety incident that has occurred while the patient is not under the care of the Trust.

4.3 Serious Incident
What is a Serious Incident?
In broad terms, serious incidents are events in healthcare where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation’s ability to deliver ongoing healthcare.

The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list.

The definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that rely on the judgement of the people involved.
4.3.1 Serious Incidents (SI) definition

Serious incidents in the NHS include:

1. Acts and/or omissions occurring as part of NHS healthcare (including in the community) that result in:

2. Unexpected or avoidable death of one or more people. This includes suicide/self-inflicted death; and homicide by a person in receipt of mental healthcare within the recent past

3. Unexpected or avoidable injury to one or more people that has resulted in serious harm;

4. Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
   - the death of the service user; or
   - serious harm;

5. Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
   - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
   - where abuse occurred during the provision of NHS-funded care.

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS-funded care caused/contributed towards the incident.

6. An incident (or series of incidents) that prevents, or threatens to prevent, an organisation’s ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
   - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;
   - Property damage;
   - Security breach/concern;
   - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
   - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA, DOLS);
   - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services; or
   - Activation of Major Incident Plan (by provider, commissioner or relevant agency)
7. Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

8. Information governance serious incident
   - This type of incident will typically breach one of the principles of the Data Protection Act and/or the Common Law Duty of Confidentiality.
   - This includes unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people’s privacy.
   - Personal data breaches which could lead to identity fraud or have other significant impact on individuals.
   - Applies irrespective of the media involved and includes both electronic media and paper records relating to staff and service users.
   - When lost data is protected e.g. by appropriate encryption, so that no individuals’ data can be accessed, then there is no data breach though there may be clinical safety implications that require the incident to be reported down a different route.

9. Information governance cyber SI
   - A cyber related incident is anything that could (or has) compromised information assets within Cyberspace. 'Cyberspace is an interactive domain made up of digital networks that is used to store, modify and communicate information. It includes the internet, but also other information systems that support our businesses, infrastructure and services'.

   It is expected that the type of incidents reported would be of a serious enough nature to require investigation by the organisation:
   - Denial of service attacks
   - Phishing emails
   - Social Media Disclosures
   - Website defacement
   - Malicious internal damage
   - Spoof website
   - Cyber bullying

10. A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death currently including:
   - Wrong site surgery
   - Wrong implant prosthesis
   - Retained foreign object post procedure
   - Mis-selection of strong potassium containing solution
   - Wrong route administration of medication
   - Overdose of insulin due to abbreviations or incorrect device
   - Overdose of methotrexate for non cancer treatment
   - Mis-selection of high strength midazolam during conscious sedation
   - Failure to install functional collapsible shower or curtain rails
- Falls from poorly restricted windows
- Chest or neck entrapment in bedrails
- Transfusion or transplantation of ABO – incompatible blood components or organs
- Misplaced naso- or oro-gastric tubes
- Scalding of patients
- Unintentional connection of a patient requiring to an air flow meter
- Undetected oesophageal intubation

**Serious Harm**

- Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care);
- Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery); or
- Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).

4.4 **Other incidents requiring investigation**

4.4.1 All incidents that are graded orange and above require some level of investigation. The detail of the investigation required for these incidents will be approved by the Chief Nurse or Medical Director.

4.4.2 Near misses that had the potential to cause significant harm will also require an investigation. It is the responsibility of the manager signing off the incident to decide on the level of investigation required.

5. **BEING OPEN**

5.1 Being open is a set of principals that healthcare staff should use in communication with patients, their families and carers following a patient safety incident in which the patient was harmed.

6. **STATUTORY DUTY OF CANDOUR**

6.1 Duty of Candour is a statutory requirement to ensure that the Being Open / Duty of Candour Policy is followed when a patient safety incident occurs resulting in moderate harm, severe harm or death.

6.2 The patient or their family/carer must be informed that a suspected or actual patient safety incident has occurred within at most 10 working days of the incident being reported to local systems (Datix).

6.3 The initial notification must be verbal (face to face where possible). The verbal notification must be accompanied by an offer of written notification. The notification must be recorded for audit purposes.

6.4 An apology must be provided – a sincere expression of sorrow or regret for the harm caused must be provided verbally and in writing.
6.5 A step by step explanation of what happened in plain English based on fact must be offered as soon as is practicable. This may constitute an initial view pending an investigation, but patients and families must be kept informed of the process.

6.6 Any incident investigation reports must be shared with the patient / family within 10 working days of being signed off as complete and the incident closed by the relevant authority.

6.7 If the requirements of the contractual Duty of Candour are not met the Commissioners can withhold the cost of an episode of care or implement a fine. They may also do any/all of the following:

- Send a report to the CQC
- The CQC can prosecute for a breach of part of the regulation and can move directly to prosecution without first serving a Warning Notice. Additionally the CQC may also take other regulatory action.
- Require that the Chief Executive send an apology and an explanation of the breach to the patient/relatives
- Publish details of the breach on the Trust website

7. OPENNESS TRANSPARENCY AND CANDOUR

7.1 Following the Francis Report (2013) it is a requirement for clinicians to be candid with patients about avoidable harm and for safety concerns to be reported openly and truthfully. The Royal Marsden must be accurate, candid and must not provide misleading information to the public, regulators and commissioners.

7.2 Definitions

- Openness - enabling concerns and complaints to be raised freely without fear with questions asked being answered.
- Transparency - accurate information about performance and outcomes to be shared with staff, patients, the public and regulators
- Candour - any patient harmed by a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made.

7.3 Principles of openness, transparency and candour

The Royal Marsden and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest open and truthful.

7.4 Candour about harm

Where death or serious harm has been or may have been caused to a patient by an act or omission of the Royal Marsden, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information.
8. ROLES AND RESPONSIBILITIES

8.1 All Employees
All employees have a duty to report incidents.
- Something that has happened that is contrary to the Trust’s specified standards of care.
- An incident in which an individual has been or could have been injured.
- An incident that places or has placed individuals at unnecessary risk.
- An incident that could put the Trust in an adverse legal or media position.

All employees are also responsible for completing the appropriate sections of the incident form, assisting with any incident investigation and, taking all reasonable steps to minimise risk.

8.2 Chief Nurse / Director Infection Prevention and Control (DIPC)
The Chief Nurse is the Executive Director responsible for all risk management within the Trust and is responsible for:
- Verifying and grading SIs and deciding of the level of investigation required for all incidents graded orange and above
- Nominating a lead investigator for formal incident investigations
- Nominating panel members for formal investigations
- Ensuring that all formal investigations are consistently managed and action plans implemented
- Nominating a deputy to fulfil their role in relation to this policy in their absence
- Trust Caldicott Guardian
- Deputising for the Trust Senior Information Risk Officer (SIRO).

8.3 Medical Director
The Medical Director is responsible for confirming the grade of medical incidents and for giving professional advice on significant incidents and SIs with medical impact or concern. The Medical Director may also nominate lead investigators and panel members for incident investigations and may be involved in the grading of SIs.

8.4 Clinical Site Practitioner / Out of Hours Cover
Out of hours cover for verification of SIs and the confirmation of medical incidents as an SI is provided by the Silver Command for the hospital which is usually the member of Clinical Executive on call. The Clinical Site Practitioner (bleep 017 Sutton and bleep 022 Chelsea) is responsible for informing the Silver Command who will advise the Gold Command if required.

In the Community the Out of Hours manager can be contacted via Mascot telecare on 0300 011 4053.
8.5 **Chief Operating Officer (COO)**

The COO is the Trust Senior Information Risk Officer (SIRO) and reviews all incidents involving cyber security, data loss or breaches of confidentiality. The SIRO is responsible for confirming any incidents as SIs that fall into the categories identified in the Department of Health Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation (May 2015). In his/her absence this duty will be performed by the Caldicott Guardian. The SIRO will deputise for the Caldicott Guardian in his/her absence.

8.6 **Divisional Directors / Clinical Nurse Directors / Clinical Directors / Matrons**

- Are responsible for receiving incident reports for the relevant divisions.
- Reviewing the incident reports and verifying the risk rating.
- Ensuring that very low and low risk incidents (green and yellow) have been appropriately investigated at ward/department level and all relevant actions noted and implemented.
- Ensuring that moderate (orange) incidents have been thoroughly investigated (root cause analysis) and appropriate risk control actions noted, implemented and discussed at divisional meetings.
- Ensuring that potentially serious incidents and SIs are reported in accordance with this policy.
- Disseminating learning objectives from reported incidents and facilitating feedback to all relevant parties.
- Ensuring that patients, relatives and staff involved are kept informed of progress regarding incidents concerning them as appropriate and before any media coverage. For patients the Consultant in charge of the patient’s care is responsible for giving this information. Guidance is given in Appendix C.

8.7 **Lead Investigator**

The Investigator appointed for formal incident investigations will be responsible for:

- Initiating and ensuring that there is a complete, secure contemporaneous record of events from the time the incident is first reported.
- Undertaking Root Cause Analysis and completing a chronology of events.
- Ensuring sufficient evidence, verbal or written, is available for the panel.
- Forwarding to the Head of Risk Management all relevant documentation for filing at the end of the investigation.
- Ensuring persons involved in the incident are kept informed of progress.
- Involving patients in the investigation process if it is appropriate.

8.8 **Public Relations/Communications Manager**

In liaison with the lead Investigator the PR/Communications Manager will:

- Co-ordinate both internal and external Public Relations issue relating to SIs.
- Draft and, when directed by the Chief Executive issue press releases.
- Co-ordinate all dealings with the Media.
- If multiple enquiries are likely then the Trust’s Emergency Command and Control Room and Hotline Procedures will be initiated.
8.9 Ward/Departmental Managers
Are responsible for:
- Ensuring that incident report forms are fully completed with all relevant details.
- Ensuring that all staff are aware of their responsibilities and that they are adhering to the reporting procedures.
- Ensuring that the patients, relatives and other persons who need to have details of the event receive timely and adequate explanation from appropriate members of staff.
- Identifying the priority of the incident and initial risk rating.
- Undertaking an initial investigation into the incident.
- Initiating the Serious Incident Procedure if appropriate.
- Ensuring that appropriate preventative action has been taken.
- Determining the probable underlying root causes of the incident.
- Forwarding the Incident Report Form to the relevant Director/General Manager/Clinical Director or Clinical Nurse Director within 24 hours of the event.

8.10 Head of Risk Management
The Head of Risk Management is responsible for:
- Day to day management of the incident system and providing regular reports to the Integrated Governance and Risk Management Committee (IGRM) for discussion and review.
- Reporting SIs to the Clinical Commissioning Group (CCG) during normal working hours.
- Convening an investigation panel to review the incident within the required timeframe – within 4 weeks of the incident being reported.
- Ensuring the meeting of the panel is documented and an Action Plan formulated as part of this documentation.
- Providing professional risk management advice to investigators and assisting investigators during Red/SIs and other investigations.
- Maintaining a record of all formal investigations and providing regular reports to the IGRM, Clinical Advisory Group (CAG), Nursing, Radiography, and Rehabilitation Advisory Committee (NRRAC) and Sisters Meetings on SIs and other significant incidents.
- Liaising with other staff who may be involved as a result of incidents, e.g. the Head of Clinical Legal Services, Complaints and Patient Information and Radiation Protection Advisor.
- Informing the Director of Medical Education of any serious incidents involving doctors in postgraduate training.
- Submitting the final report from SI investigations to the CCG and Monitor.

8.11 Clinical Risk Advisors
Are responsible for supporting the Chief Nurse and Head of Risk Management in their duties and deputising in the absence of the Head of Risk Management.
8.12 Patient Safety Analytics Manager / Deputy Head of Risk Management
- The Patient Safety Analytics Manager / Deputy Head of Risk Management is responsible for maintaining and supporting the incidents, complaints and claims modules.
- Providing a quarterly report on all staff and patient accidents to the Trust’s IGRM and The Quality, Assurance and Risk Committee (QAR) and the Head of Risk Management.
- Provision of reports from the Datix system to all relevant parties.

8.13 Health and Safety Advisor
The Health and Safety Advisor will be responsible for:
- Reporting all RIDDOR incidents (as defined in Appendix D) to the HSE and for investigating such incidents with the relevant head of department. A copy of the final report to be provided to the Trust’s Health, Safety and Security Committee.
- Providing support for H&S and non-clinical related incident investigations.

8.14 Datix Administrator
The Datix Administrator will be responsible for:
- Maintaining a central database (Datix) of all reported accidents/incidents.
- Maintaining a central library/archive of all reported accident/incident forms.
- Provision of reports from the Datix system to all relevant parties.
- Providing administrative support to the incident panel meetings.
- Provides support for incidents, complaints and claims modules.
- Provision of reports from the Datix system to all relevant parties.
- Report patient safety incidents to the NRLS.

8.15 Director of Medical Education
The Director of Medical Education will be responsible for reporting SIs that involve doctors in post graduate training to the London Deanery via the Serious incident portal.

8.16 Convenor for Radiology Discrepancy Meetings
The convenor for the discrepancy meeting is responsible for ensuring that cases that are identified to have caused harm or delayed treatment are reviewed and escalated appropriately and are entered onto Datix.

8.17 Occupational Health Department
The Occupational Health Department will be responsible for reporting any occupational diseases under RIDDOR. All reports to be copied to the Health and Safety Advisor.

8.18 Information Governance Manager
The Information Governance Manager is responsible for reviewing information governance incidents on Datix and grading and reporting applicable IG incidents as required by: DH Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation (May 2015).
8.19 Head of the Stem Cell Laboratory
The Head of the Stem Cell Laboratory is the Human Tissue Authority (HTA) Designated Individual (DI) and is responsible for reporting all Human Tissue Authority (HTA) adverse events and reactions within 24 hours to the HTA. The HTA Person Designate (PD) who is the Deputy Head of the Stem Cell Lab may also report to the HTA.

8.20 Trust Safeguarding Leads for Adults and Children
The Trust Safeguarding leads for adults and children are responsible for reviewing all incidents that involve safeguarding issues and escalating appropriately as identified in the Trust Safeguarding Policies and Procedures.

8.21 The Integrated Governance and Risk Management Committee (IGRM)
- The IGRM will review and approve formal incident reports including SIs.
- Monitor implementation plans from incident reports.
- Disseminate learning objectives from reported incidents.
- Make reports to the Quality, Assurance and Risk Committee (QAR).
9. PROCEDURES

9.1 PROCEDURES FOR REPORTING INCIDENTS – ALL INCIDENTS

The following two procedures detail the process for all incidents. The electronic incident form is available on the hospital intranet or via the Datix desktop link.

Incident Reporting Flowchart for Green and Yellow Incidents

Accident/Incident Form completed within **24 hours** of incident.
Risk Management team perform an initial review with one working day

Form passes electronically to line manager as soon as completed and should be acknowledged within **48 hours**

Line manager investigates and completes Management Action and Risk Rating within **21 days**
or refers to their line manager if unable to risk rate -

- **yellow/green rated incident**
  - Local investigation if manager decides it would be useful

- **Near Misses**
  - Local investigation required with senior management review and root cause analysis where there was potential for significant harm

Management sign off should be completed in **7 days**

Accident/Incident form finally reviewed by Risk Management Team within **5 days** of notification that the incident is ready for final approval

- Risk Management Team ensure reporting to external agencies is carried out as required

- Head of Risk Management regularly reviews trends of incidents in terms of type and area and reports regularly to departments and **quarterly** to IGRM via the Integrated Governance Monitoring Report. Action is taken when trends indicate a persistent problem.

The Datix system is set up to automatically to refer incidents of specific types/severity to the appropriate manager/leads in order that the appropriate review is undertaken, external reporting if applicable and follow up monitored.
Procedure for the follow up of Incidents requiring formal investigations, including Serious Incidents:

**Timeframe** Incident Occurs

Immediately  Make all involved safe, inform Line Manager & complete an incident form

30 Minutes  Line Manager contacts Clinical Nurse Director or Divisional Director who reports to:

1 Hour  Chief Nurse (or deputy). Medical Director for verification of the grade. Clinical Site Practitioner (out of hours) informs the Silver Command for verification of the grade.

24 Hours  SI or formal investigation status confirmed. Initial lead investigator appointed by manager confirming the SI. Lead investigator co ordinates the investigation, supports staff and obtains statements from those involved.

24 Hours  In the event that staff support is required it is the responsibility of the lead investigator to advise staff support of all staff involved including medical staff.

24 Hours  Reported to Risk Management who reports to NRLS, Commissioners and CCG if an SI within 48 Hours.

48 Hours  Risk Management confirms whether a 72 hour review is required / membership of the Incident panel with Chief Nurse or Deputy.

48 Hours  Risk Management informs Chair of the panel within 48 Hours.

48 Hours  Lead Investigator confirms electronic incident form has been completed.

If an initial review meeting is required in order to facilitate immediate action this is organised by the lead investigator.

Risk Management team arranges panel meeting to be held within 30 working days of the incident. If there are problems associated with panel members’ availability Risk Management will contact the Chief Nurse/Medical Director within one week to seek alternative members.

All staff that provide statements or are to be interviewed are supported by an appropriate manager. They are contacted individually through their manager and are informed in writing of the panel requirements prior to the meeting.

Any junior doctor involved in an incident that it is required to provide a statement will be supported appropriately by their Clinical Tutor and/or the Director of Education

72 Hours  If required a meeting will be held to review the findings of the 72 hour review

30 Days (1 Month)  Panel meets and Risk Management is responsible for recording the notes of the meeting.
32 Days Draft notes of the meeting and draft final report are circulated to the panel members within two days of the panel meeting.

37 Days Panel to respond to Risk Management within one week.

40 Days Approved notes of the meeting and final report are circulated to the panel and anyone named on the action plan in order that responsibilities are acknowledged and actions can commence. Feedback is also given to the area involved in the incident.

45-60 Days Report containing summary of the incident, panel discussion and the action plan is generated by Risk Management and submitted at the next available IGRM.

Once approved by IGRM the report is circulated to all involved in the incident review process and the CCG if an SI and any other interested parties such as patients or relatives. At this time information may also be added to relevant training programmes to ensure that Trust wide learning ensues. Reports are also circulated to relevant committees and appropriate circulation list. The Director of Medical Education is responsible for reporting SIs that involve doctors in post graduate training to the London Deanery via the Synapse reporting system.

The incident data base is updated by Risk Management with all papers being uploaded onto the electronic system.

The report is submitted to the CAG and NRRAC and circulated widely across the organisation.

The incident is added to the Incident follow up table. This is submitted to IGRM on a quarterly basis until all actions are completed.

Once all actions are completed the incident data base is updated and the incident is closed.

All appropriate sections of the report form should be completed. Writing should be clear and legible and should state only FACT not OPINION.

All RIDDOR category incidents (Appendix D) should be immediately reported by telephone by the Head of Department, Ward Sister/Charge Nurse (or deputy) to the Health & Safety Advisor who will be responsible for reporting any RIDDOR incidents to the HSE.

9.2 SPECIFIC PROCEDURES FOR REPORTING ACCIDENTAL EXPOSURES TO BLOOD, BODY FLUIDS AND SHARPS

9.2.1 For all needlestick injuries, the injured person should follow the Trust’s procedure “Blood-Borne Viruses: Prevention of Infection (Inoculation Injury (Needlestick) Procedures)”, policy no. 181.
9.2.2 All incidents involving exposure to blood, body fluids and sharps should be immediately reported to the Head of Department, Ward Sister/Charge Nurse (or their designated deputy). Out of hours (including evenings, weekends and bank holidays) incidents should be reported to the Clinical Site Practitioner 017/022 bleep holder immediately.

9.2.3 The incident should be immediately reported by telephone to the Occupational Health Department Sharps Hotline (Sutton 3558, Chelsea 2658) and advice sought as necessary. Out of hours there is a voicemail message giving precise information on the action to take following an accident.

9.2.4 For all sharps injuries a standard electronic Incident Report Form should be completed. For all used sharps injuries or incidents involving exposure to blood or body fluids, the injured person should also complete a Microbiology Needlestick Form.

9.2.5 The injured person should then take the Microbiology Needlestick Review Form together with any appropriate blood samples, to the Microbiology Department.

9.2.6 Microbiology will complete the relevant sections (Part 6) of the form and will forward the completed document to Occupational Health. Microbiology will also inform the Consultant Microbiologist or Infection Prevention and Control Nurse.

9.2.7 Occupational Health will retain the form in the staff member’s confidential records.

9.2.8 As appropriate, RIDDOR incidents (Appendix D) will be immediately reported to the Health and Safety Advisor who will make sure that the incident is reported to the Health and Safety Executive.

9.3 REPORTING MEDICAL DEVICE INCIDENTS

9.3.1 Where an incident (or potential incident) involves a suspected fault or failure of a medical device, specific device details must be recorded in the correct section of the incident form. A description of an adverse incident involving a medical device is provided in Appendix E.

9.3.2 The device involved in the adverse incident should be immediately placed out of use and any relevant packaging retained. The device should be clearly labelled “DO NOT USE DEVICE UNDER INVESTIGATION FOLLOWING INCIDENT”.

9.3.3 Where the device requires inspection, the Trust procedures for the Decontamination of Medical Devices prior to inspection, service or repair must be followed. A Device Fault Card (available on all wards) should be completed and attached to any medical device being sent for repair, investigation and inspection.

9.4 REPORTING CONTROLLED DRUG (CD) INCIDENTS

9.4.1 If a discrepancy or incident relating to controlled drugs is identified then it should be reported on the internal incident reporting system in accordance with local procedures and also the Chief Pharmacist and Accountable Officer informed.
9.5 REPORTING SECURITY INCIDENTS

9.5.1 All security incidents should be verbally reported to the Portering/Security Manager or his/her designated deputy. As appropriate, the Portering/Security Manager (or designated deputy) will ensure that the incident is reported to the Police. An incident form should also be completed electronically for all security related incidents wherever possible.

9.5.2 Out of hours, security incidents should be reported to the 022/017 bleep holder. The bleep holder will report the incident to the Police and inform the on call Divisional Nurse Director and on call Facilities Manager as appropriate.

9.5.3 Relevant security incidents are reported to the NHS Business Services Authority Security Incident Reporting System (SIRS) by The Royal Marsden Security Team. These are incidents that fall into the following categories:

- Any security incident involving physical assault of NHS staff
- Non-physical assault of NHS staff (including verbal abuse, attempted assaults and harassment)
- Theft of or criminal damage (including burglary, arson, and vandalism) to NHS property or equipment (including equipment issued to staff)
- Theft of or criminal damage to staff or patient personal property arising from these types of security incident

9.6 REPORTING RADIATION INCIDENTS

9.6.1 The usual Trust process for incident reporting should be followed and the Radiation Protection Supervisor (RPS) for the department should be made aware of all reported radiation incidents. In the event that the incident is graded Orange and above, advice should also be sought from the Radiation Protection Advisor (RPA).

9.6.2 Incidents involving ward areas or staff should also be reported to the CNS Radiation Protection and an incident form should also be completed.

9.7 RADIOTHERAPY SERVICE REPORTING

Additional information and guidance on managing incidents (non-conformity) specifically in Radiotherapy are included in the ISO9001:2008 Accredited Quality Management System and the National Guideline ‘Towards Safer Radiotherapy’ (TSR) 2008.

9.7.1 Usual Trust processes for incident reporting are followed and in addition radiotherapy incidents (non-conformity) are reported voluntarily into ISO9001 and TSR systems. Corrective/preventative actions are monitored and trends are additionally analysed and discussed at the Multiprofessional Quality Assurance in Radiotherapy Committee (MPTQART) every two months.
9.8 REPORTING INCIDENTS IDENTIFIED AT RADIOLOGY DISCREPANCY MEETINGS

9.8.1 The Standard Operating Procedure for learning from discrepancy meetings identifies the process by which incidents will be reported onto the Datix system and reviewed appropriately.

9.9 REPORTING INCIDENTS OF VIOLENCE AND AGGRESSION TO STAFF

9.9.1 Additional information and guidance on managing incidents of violence and aggression at work are provided in the Trust Policy “Challenging Behaviour, Violence and Aggression from Patients and Visitors - Policy and Procedure for the Management of”.

9.9.2 All incidents involving physical assault must be reported immediately to the Divisional Directors/Nurse Directors. The Head of Facilities will also be informed of all incidents involving physical assault.

9.10 REPORTING INCIDENTS INVOLVING LONE WORKERS

9.10.1 Additional information and guidance on what constitutes a lone working incident and prompts for staff on what to report are provided in the Trust Lone Worker Policy.

9.10.2 Staff must be encouraged to report all incidents and near misses that occur while working alone. Staff should not allow a presumption that ‘it is part of the job’ to stop them completing a report.

9.11 REPORTING ADVERSE TRANSFUSION EVENTS

9.11.1 Any adverse event related to the transfusion of blood or one of its components (platelets, FFP, cryoprecipitate, cryo poor plasma, buffy coat / granulocytes) may need further investigation.

9.11.2 As soon as the immediate risk to the patient / staff has been managed details of the incident must be reported and recorded as a matter of urgency. A full incident report form must always be completed electronically and include all relevant details.

9.11.3 The Blood Bank and/or Transfusion Practitioner at the relevant site must also be informed as soon as possible after the event has been discovered.

9.11.4 The Laboratory Manager or Transfusion Practitioner is responsible for forwarding the details of any such incidents to the relevant external bodies that monitor the safety of blood transfusion nationally; Serious Hazards of Transfusions (SHOT) and MHRA (SABRE).

9.11.5 The Trust Hospital Transfusion Committee (HTC) will review all such errors or adverse incidents and where appropriate, recommendations and changes to practice will be made. The HTC will regularly report all such incidents to IGRM.
9.12 REPORTING SERIOUS INCIDENTS INVOLVING DOCTORS IN POST-GRADUATE TRAINING

9.12.1 The Director of Medical Education is responsible for reporting SIs that involve doctors in postgraduate training to the London Deanery via the Trainee Revalidation Employer Portal.

9.12.2 The London Local Education and Training Boards (LETBS) expect to be immediately notified where it has been identified that a doctor in postgraduate training has been involved in a serious incident. The Trust will adhere to (via the Director of Medical Education) the current guidance as issued by the three London Local Education and Training Boards in relation to SI reporting.

9.12.3 Their involvements may be graded in the following ways:
- Present at the time, not directly involved in the incident, but personally affected by the incident
- Involved but in a minor way, for example as part of the team
- Directly involved as contributing to the incident
- Directly implicated in the response to and management of the incident
- A combination of the above

9.12.4 Any junior doctor involved in an incident that it is required to provide a statement will be supported appropriately by their Clinical Tutor and/or the Director of Medical Education.

9.13 REPORTING INCIDENTS INVOLVING PATIENTS PARTICIPATING IN A RESEARCH TRIAL

9.13.1 The Research & Development Department are notified through Datix regarding incidents involving patient participating in clinical trials.

9.14 REPORTING INCIDENTS INVOLVING INFORMATION GOVERNANCE AND CYBER SECURITY INCIDENTS

9.14.1 The Information Governance Manager is responsible for reviewing information governance incidents on Datix and grading and reporting applicable IG incidents in accordance with the requirements of the Information Governance Policy and Procedure. Failure to comply with this policy may result in breaching the GDPR/Data Protection Act (and other legal and regulatory) requirements, resulting in a fine from the Information Commissioner of up to €20m or 4% turnover, whichever is the higher. Where there is a breach of confidentiality or loss/unavailability of data or information asset, this must be reported and managed via the incident reporting process.

9.15 REPORTING INCIDENTS INVOLVING PATIENTS INVOLVED IN A NATIONAL NHS SCREENING PROGRAMMES

9.15.1 UK National Screening Committee has issued interim guidance – Managing Incidents in National NHS Screening Programmes (2013).

9.15.2 The Trust will comply with the requirements of this guidance where possible and work with the bodies concerned to meet their reporting requirements.
10. **GRADING INCIDENTS**

10.1 In order to ensure equality in incident investigations, the Trust will adopt a standard Risk Rating system for all incidents.

10.2 For continuity the risk rating system will be of a similar type of system that used for the completion of risk assessments.

10.3 Full details of the Trust’s procedures for grading incidents are provided in Appendix A.

10.4 The risk rating of incidents will comply with reporting requirements. IG and Cyber incidents will be reviewed by the Information Governance Manager and graded according to the Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation.

10.5 The grading of serious incidents is undertaken by the Chief Nurse or Medical Director and will reflect the requirements of the Serious Incident Framework.

10.6 All SIs and formally investigated incidents will be subject to root cause analysis, see Investigation of Incidents, Complaints and Claims Policy.

11. **FORMAL INVESTIGATION PANELS**

11.1 **Preparation**

(Also see Policy for the Investigation of Incidents, Complaints and Claims for information on incident investigation).

11.1.1 The lead investigator and appropriate membership of the investigation panel is allocated by the Chief Nurse / Medical Director. The Chair is chosen from outside the clinical area where the incident occurred but is preferably someone who has some specialist knowledge about the specifics of the incident.

11.1.2 If the investigation:

- Is into a Serious Incident
- Has a subject matter involving clinically related issues that is not capable of resolution without an expert clinical opinion.
- Raises substantive issues of professional misconduct or the performance of senior managers.
- Involves issues about the nature and extent of the services commissioned.
- Involves another Trust and requires a joint investigation.

The Medical Director or Chief Nurse under the leadership of the Chief Executive will make a decision regarding the extent of the investigation, whether a 72 hour review is required and the involvement of external panel members depending on the individual circumstances of the event.
11.1.3 72 Hour Review is an initial review of the incident to:
- Identify and provide assurance that any necessary immediate action to ensure that the safety of staff, patients and the public is in place.
- Assess the incident in more detail to confirm if the incident meets the criteria for a serious incident or an incident that requires a full investigation.
- Propose the appropriate level of investigation

11.1.4 The lead investigator is a senior manager from the Division in which the incident occurred and other members of the panel will be decided with regard to the individual circumstances of the incident. It is important to remember that panel members should not be chosen from the area in which the incident occurred in order that completely impartial decisions can be made. It may also be necessary to involve someone external to the organisation in some incidents.

11.1.5 The lead investigator is responsible for conducting the detailed investigation and providing the information to the Risk Management Team in a timely manner (see 9.1) If an initial review meeting in the first week is considered necessary in order facilitate immediate action it is the responsibility of the lead investigator to arrange this.

11.1.6 There will be a member of the Risk Management Team on each panel and the minutes of the meeting and the final report are the responsibility of Risk Management.

11.1.7 Once statements and supporting information have been received by Risk Management, copies will be sent to the chair of the panel in order that they can decide if there are staff that they wish to attend the meeting (this can only be facilitated if investigation results are received within three weeks).

11.1.8 Any staff that are required to attend will be contacted as soon as possible in order that they can make arrangements to be available. Staff will be supported during this process by their manager. Support is also available from the Occupational Health Department and Staff Support Facilitator. (Further information can be found in the ‘Supporting Staff Involved in Potentially Traumatic or Stressful Incidents, Complaints, Claims Policy’, section 5; process for supporting staff involved in traumatic/stressful incidents, complaints or claims).

11.1.9 Supporting information such as statements, incident forms and root cause analysis tools are circulated to the panel in advance of the meeting.

11.2 Investigation Panel Process

11.2.1 The panel meets and the Lead Investigator presents the case and outlines the events surrounding the incident.

11.2.2 Supporting documentation is discussed and reviewed. Any staff members that have been requested to attend are interviewed in order that any additional information may be forthcoming.
11.2.3 It is important to remember that staff may find this process difficult and much reassurance is given to ensure that staff are aware that this process is to find out exactly what happened rather than apportioning blame. At the end of the interview staff are informed about the process that will follow and that their involvement is at an end.

11.2.4 The investigation panel will have further discussion and if necessary request further information.

11.2.5 Recommendations for action will be made if appropriate and these will be noted in the minutes ensuring that all members of the panel are in agreement.

11.3 Pressure Ulcer Panels

11.3.1 All pressure ulcers grade 3 and 4 that are acquired under the care of the Trust are investigated using the route cause analysis tool and are reviewed at the monthly pressure ulcer panel meetings. If a category 4 PU results in serious harm or death and meets the NHS England SI framework definition of a serious incident the incident will also be reported on STEIS and the panel meeting will be chaired by the Chief Nurse.

11.3.2 Summary reports and action plans of Category 4 pressure ulcers are reviewed at the Integrated Governance and Risk Management Committee. Category 3 reports are reviewed at the Tissue Viability Committee.

12. LEARNING FROM INCIDENTS AND PROMOTING IMPROVEMENTS IN PRACTICE

12.1 Minor incidents graded green and yellow are reviewed at departmental level. It is the responsibility of the head of department to instigate discussion / action as result of incidents. This is an integral part of the risk management process and a regular incident review session should be included at ward and department meetings. The Risk Management Team and Clinical Nurse Directors will provide support and advice in order to establish the regular review of minor incidents and the resulting improvements in practice.

12.2 Moderate incidents graded Orange, require a more involved investigation and will need action to establish the root cause of the event. This investigation may be a formal investigation and follow that process or may be lead by a manager within the division involved and the outcome will be reviewed at both departmental and divisional level with learning points being disseminated across the division. Any investigations that result in actions that have Trust wide learning points will be brought to the IGRM.

12.3 Major incidents and SIs are subjected to a formal investigation (see this policy and the Investigation of Incidents, Complaints and Claims Policy)

i) The actions produced as a result of a formal incident investigation are agreed by all those identified to take forward an action.

ii) The resulting report goes to IGRM for approval and dissemination of learning points.
iii) For SIs once the final report is approved the CCG and STEIS data base is updated to inform external stakeholders such as the commissioners of the results of the investigation and the root causes.

iv) The report for formal investigations are circulated internally to all those involved in the investigation and to CAG, NRRAC, Surgical Audit Group, Sisters Meetings and Mandatory Training for relevant staff to disseminate the learning points identified. Reports are also discussed at Divisional Boards.

v) All action points from significant incidents are entered onto a review chart held by the Risk Management Team. This document is updated regularly and submitted to IGRM every three months.

vi) Actions are removed once all recommendations have been completed.

vii) Summary report formal incident investigations are included in the incident review data in the quarterly Integrated Governance Monitoring Report. This report is available to all stakeholders.

viii) Periodic audit is undertaken to ensure that the recommendations made as a result of incidents are being upheld.

12.4 Learning from research incidents and audits undertaken by the GCP will be fed back through the research teams.

13. **EXTERNAL REPORTING OF SERIOUS INCIDENTS**

13.1 All SIs must be reported to the Strategic Executive Information System (STEIS) and the National Reporting and Learning System (NRLS) within 48 hours, or within 2 hours if the item is highly sensitive or newsworthy.

13.2 The information is entered by completing the electronic incident form on the STEIS data base and uploading the Datix incident form to the NRLS. An automated email goes from STEIS to NHS England (London) or the South London Commissioning Support Unit (SLCSU) to alert them that an SI has been reported.

London Patient Safety England reviews hospital SIs and their contact email is london.patientsafetyengland@nhs.net
Their telephone number during weekday office hours is 020 3182 4972.

South London Commissioning Support Unit (SLCSU) reviews Community SIs and their contact email is SLCSU.SI@nhs.net.
Their telephone number during weekday office hours is 020 3049 4290.

13.3 **Out of Hours**
In the event that the incident falls into the Emergency Planning escalation criteria out of hours support can be sought on NHSE Gold phone 08448 222888 and ask for NHS01.

13.4 **Information Governance SIs**
Will be reported by the Information Governance Manager on the IG Toolkit Incident reporting Tool as well as STEIS.
13.5 Clinical Trials
SIs relating to patients participating in clinical trials should be notified to the Principal or Chief Investigator of the clinical trial and to the Assistant Director of Clinical Research and Development using the SI form. The Principal/Chief Investigator should identify whether the SI constitutes a serious breech of Good Clinical Practice (GCP) and report the breech to the MHRA in accordance with the Research Standard Operating Procedure for Notification of Serious Breaches of GCP in Royal Marsden Hospital/Institute of Cancer Research Sponsored Drug Trials ref gSOP-10-1’.

13.6 Care Quality Commission (CQC) notification processes are overseen by the risk/quality teams.

13.7 The following information should be supplied:
- Initials of individuals concerned and hospital reference number
- Name of Trust
- Name of Consultant for patient involved
- Detail regarding Ward or Department and Division
- Date of Incident
- Summary of the incident

13.8 During office hours reporting is the responsibility of the Head of Risk Management, out of hours if the incident is highly sensitive or newsworthy the member of the Clinical Executive on call should consider contacting – NHSE Gold Phone on 0844 822 2888 (page one bureau) and quote NHS01

13.9 In the event that SIs require the involvement of Police or the Health and Safety Executive reference should be made to the Memorandum of Understanding - DH 2006.

The final investigation report (Appendix F), containing information on the outcome of the investigation and recommendations, should be sent to NHS London, Monitor and the commissioners within 60 days of the incident. At this time the STEIS database will also be updated.

13.10 The Head of Risk Management will keep copies of all documentation relating to SIs and formal investigations.

13.11 The Datix Administrator uploads patient safety incident data on a weekly basis and submits anonymised data to the NRLS.
### 14. STAKEHOLDER REPORTING

In addition to the National Reporting and Learning System and Commissioning Support Unit there are other external stakeholders who require, or might potentially require, information on specific incidents. Details of key stakeholders and the post holder responsible for informing them are listed below.

<table>
<thead>
<tr>
<th>External Agency</th>
<th>Type of Incident</th>
<th>Reporting Officer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Protection Agency</td>
<td>Infectious disease.</td>
<td>Chief Nurse / DIPC</td>
</tr>
<tr>
<td></td>
<td>Outbreak of Infection.</td>
<td></td>
</tr>
<tr>
<td>Confidential Enquiries</td>
<td>SI</td>
<td>Lead investigator</td>
</tr>
<tr>
<td>Coroner</td>
<td>SI</td>
<td>Lead investigator</td>
</tr>
<tr>
<td>Department of Health</td>
<td>Fire Incident</td>
<td>Fire Safety Officer</td>
</tr>
<tr>
<td>Care Quality Commission</td>
<td>Ionising Radiation Incident. (IRMER) SIs Pressure ulcers</td>
<td>Radiation Protection Advisor. Head of Risk Management via NRLS</td>
</tr>
<tr>
<td>Health and Social care Information Centre</td>
<td>Information Governance SIs</td>
<td>Information Governance Manager, via Information Governance Toolkit</td>
</tr>
<tr>
<td>Medicines and Healthcare products Regulatory Agency (MHRA)</td>
<td>Medical Devices Incident. Defective Medicines Serious breach in GCP relating to clinical trials Medical Devices Incidents – Radiotherapy Incidents</td>
<td>Head of Risk Management Nurse lead for Intravenous Therapy or Device Coordinator. Chief Pharmacist Assistant Director of Clinical R&amp;D Head of Radiotherapy Physics</td>
</tr>
<tr>
<td>NHS Resolution</td>
<td>Potential Litigation</td>
<td>Head of Clinical Legal Services, Complaints and Patient Information</td>
</tr>
<tr>
<td>Police</td>
<td>Theft, Violence</td>
<td>Lead investigation/Senior Manager</td>
</tr>
<tr>
<td>Professional Regulatory body e.g. GMC, NMC</td>
<td>Breech of professional code of conduct.</td>
<td>Chief Nurse, Medical Director</td>
</tr>
<tr>
<td>London Deanery</td>
<td>SIs Involving Trainees</td>
<td>Director of Medical Education or Specialist Registrar Director</td>
</tr>
<tr>
<td>Health and Safety Executive</td>
<td>RIDDOR Incident. Ionising Radiation Incident (Equipment Issues)</td>
<td>Risk Management Radiation Protection Advisor</td>
</tr>
<tr>
<td>Human Tissue Authority (HTA)</td>
<td>Stem Cell Tissue for post mortem</td>
<td>Head of Stem Cell Laboratory Pathology Service Manager</td>
</tr>
<tr>
<td>Serious hazards of transfusion committee (SHOT). Serious adverse blood reactions and events (SABRE)</td>
<td>Blood transfusion incident.</td>
<td>Lead BMS / Blood Transfusion Quality Manager</td>
</tr>
<tr>
<td>NHS Security Management Service. This is via the SIRS reporting system</td>
<td>Incidents of actual violence to staff</td>
<td>PA to Head of Facilities</td>
</tr>
<tr>
<td>Food Standards Agency</td>
<td>Food hygiene/incident.</td>
<td>Catering Manager</td>
</tr>
</tbody>
</table>
15. **MONITORING**

**Annual audit of the following:**

<table>
<thead>
<tr>
<th>Environmental Health</th>
<th>Food hygiene/safety incident.</th>
<th>Catering Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment Agency</td>
<td>Radiation incidents and any other incidents that have the potential to affect the environment</td>
<td>Radiation Protection Advisor Assistant Director of Estates</td>
</tr>
<tr>
<td>Monitor</td>
<td>Serious Incidents</td>
<td>Head of Risk Management</td>
</tr>
<tr>
<td>Commissioners</td>
<td>Serious Incidents</td>
<td>Head of Risk Management</td>
</tr>
<tr>
<td>NHS London</td>
<td>Serious Incidents Swine Flu</td>
<td>Head of Risk Management Chief Nurse</td>
</tr>
<tr>
<td>Children's social care</td>
<td>Child Protection issues</td>
<td>Lead Nurse or Doctor for Child Protection</td>
</tr>
<tr>
<td>Adult social care</td>
<td>Safeguarding adult issues</td>
<td>Trust Adult Safeguarding Lead</td>
</tr>
<tr>
<td>NHS Counter Fraud Service</td>
<td>Fraud</td>
<td>Chief Financial Officer</td>
</tr>
</tbody>
</table>

Audit of incident data to ensure that incidents are being reported in all areas by all staff

Audit of incident data to show that external reporting is undertaken
APPENDIX A

GRADING INCIDENTS

1.0 **AIM**

1.1 In accordance with statutory requirements, the Trust’s Accident/Incident Policy includes a standard method for grading the level of risk associated with each individual incident report. The aim of the grading matrix is to standardise the way in which all incidents are reported and investigated.

1.2 As previously noted, the aim of the investigation process is to identify all of the risk factors involved in the incident (principal cause and contributory factors). Effective investigation of an incident ensures that appropriate lessons are learnt from the investigation and that these are then used to improve the standard of care and safety provided for all Trust activities.

2.0 **GRADING INCIDENTS – IMMEDIATE IMPACT / OUTCOME**

2.1 The grade is calculated by comparing the Severity of the Incident against the Likelihood of re-occurrence. The procedures for grading incidents are set out as follows:

<table>
<thead>
<tr>
<th>None (green)</th>
<th>Low / Minor (yellow)</th>
<th>Moderate (orange)</th>
<th>Severe / Major (red)</th>
<th>Death / Catastrophic (red)</th>
</tr>
</thead>
</table>

2.2. An immediate assessment of the incident grade should be undertaken quickly and it is not necessary for the assessor reviewing the incident form to be in possession of all the facts at the time of this initial grading. The immediate grading should be used to identify the immediate level of investigation required. There is always scope for re-grading the incident as the facts and issues emerge.

2.3 The immediate impact severity of the incident should be graded into one of the five categories.

2.4 **Arrangements for Grading**

All staff are given instruction on the grading process at induction. Staff completing incidents forms are encouraged to complete an initial grading, which is then reviewed by the manager in charge of the area. Because of the nature of the grading process, it is essential that the managers designated to grade incidents have been trained to do so, and that their performance is periodically audited.

The Trust arranges incident reporting training for all managers, heads of departments, and head of clinical units, ward sisters/charge nurses. This training includes details on the Trust’s incident reporting policy and incident grading and investigation. Following this training managers etc. will be considered competent to undertake grading.
Before they have been trained managers will only be expected to identify the initial incident grade and use this as a guide to the immediate level of reporting and investigation required.

Notification of incidents are emailed to the Clinical Nurse Directors to be reviewed and if necessary re-graded.

All final grades will be reviewed by the Head of Risk Management, the Clinical Risk Advisor or Health and Safety Advisor who will verify the grade and monitor continuity and consistency of the grading process.

Medication incidents are reviewed by a team consisting of the Chief Pharmacist, Lead Nurse for Intravenous Therapy and other members of the Pharmacy team.

3.0 GRADING INCIDENTS – FULL RISK RATING

3.1 The full risk rating of incidents involves identifying the likelihood of reoccurrence and, the severity of the incident.

3.2 Step 1: Likelihood/Frequency Rating

What is the likelihood for reoccurrence of this event, taking into account any risk control measures implemented after the incident occurred.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rare/Improbable</td>
<td>Can't believe this will happen again. A one-off, risk cannot be reduced any further.</td>
</tr>
<tr>
<td>2</td>
<td>Unlikely</td>
<td>Remote. Do not expect it to happen again but it is possible as risk can't be further reduced.</td>
</tr>
<tr>
<td>3</td>
<td>Possible</td>
<td>May occasionally reoccur if procedures are not completed correctly or risk assessment is incomplete. 50/50 possibility that this type of event will happen again.</td>
</tr>
<tr>
<td>4</td>
<td>Likely (High Probability)</td>
<td>Probable. Will probably re-occur but is not a persistent issue.</td>
</tr>
<tr>
<td>5</td>
<td>Almost certain</td>
<td>Likely to reoccur on many occasions, a frequent issue. High priority risk assessment. Action required to further reduce risk.</td>
</tr>
</tbody>
</table>
### Step 2: Severity/Consequence

What is the actual severity of the incident?

<table>
<thead>
<tr>
<th>Description</th>
<th>Actual Impact on Individuals</th>
<th>Actual Impact on the Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Staff</td>
<td>Patients</td>
</tr>
<tr>
<td>None</td>
<td>No injury</td>
<td>No adverse outcome.</td>
</tr>
<tr>
<td>Low / Minor</td>
<td>Short term injury/damage less than 3 days sickness absence.</td>
<td>Short term injury. No permanent damage. Low radiation dose incident. Treatment amended slightly but no significant impact for patient. Medication reviewed, no significant effect on patient, medication plan amended slightly. Local infection.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Semi-permanent injury. Greater than 7 days sickness absence (RiddoR reportable).</td>
<td>Moderate harm – a) harm that requires a moderate increase in treatment, and b) significant, but not permanent harm Moderate increase in treatment means an unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area such as intensive care.</td>
</tr>
<tr>
<td>Severe/ Major</td>
<td>Permanent injury/disability/ illness</td>
<td>Potentially reportable to HSE ( Dangerous Occurrence), Local Authority (contamination of local area), Dept of Health (Radiation incident), Health Protection Agency (infection risk), Police, SHOT (Blood transfusion).</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Death / Catastrophic</td>
<td>Fatality</td>
<td>Fatality Unexpected death.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loss of essential services including medical gases.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major fire.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Significant structural damage.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major equipment failure.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major power failure.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major service disruption.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National targets not achieved for significant period.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Length of stay increased greater than 2 weeks.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Temporary service/ward closure.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High Risk.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reportable to SWLSHA, HSE, etc. Local and National publicity possible.</td>
</tr>
</tbody>
</table>

Severe

- Permanent injury, disability
- Adverse clinical outcome.
- Misdiagnosis.
- Delayed referral resulting in adverse outcome.
- Operation not intended.
- Medication incident with patient receiving >25% difference from intended dose.
- Medication increased leading to increased morbidity or mortality.
- Major intervention required following incident e.g. return to Theatre, CCU.
- Procedure involving wrong patient.
- Major outbreak of infection.
- Major food hygiene outbreak.
- Blood transfusion incident.
- Radiation dose greater than 20% above or below prescribed for a single dose or 10% over or under for complete treatment.

Death

- Unexpected death.
- As above

Catastrophic

- Fatality
- Fatality Unexpected death.
### Step 3: OVERALL RISK RATING

The overall risk rating is identified using the following risk matrix:

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>None/ Insignificant</th>
<th>Low/ Minor</th>
<th>moderate</th>
<th>Severe/ Major</th>
<th>Death/ Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain</td>
<td>5 yellow</td>
<td>yellow</td>
<td>orange</td>
<td>red</td>
<td>red</td>
</tr>
<tr>
<td>Likely</td>
<td>4 yellow</td>
<td>yellow</td>
<td>orange</td>
<td>red</td>
<td>red</td>
</tr>
<tr>
<td>Possible</td>
<td>3 green</td>
<td>yellow</td>
<td>orange</td>
<td>red</td>
<td>red</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2 green</td>
<td>green</td>
<td>yellow</td>
<td>orange</td>
<td>red</td>
</tr>
<tr>
<td>Rare</td>
<td>1 green</td>
<td>green</td>
<td>yellow</td>
<td>orange</td>
<td>red</td>
</tr>
</tbody>
</table>
APPENDIX B

Overview of the serious incident management process

1. Incident occurs
   - Report on LRMS/NRLS and to other bodies such as safeguarding lead as applicable
   - Manage in line with local risk management policy
   - Engage with those involved/affected

2. Is it a serious incident?
   - Yes: Report on STEIS
   - No: Review and discuss with commissioner
   - Unknown: Report/notify other stakeholders as required e.g. safeguarding, CQC, TDA etc.

3. Within 2 working days
   - Complete initial review and submit to commissioner where possible this should be the provider’s ‘lead commissioner’ who can liaise with others as required. This should be outlined in the RASCI model.
   - Confirm level of investigation required

4. Within 3 working days
   - Lead investigator identified. Team established. Terms of reference set. Management plan established
   - Undertake the investigation

5. 60 working days or 6 months for independent investigation
   - Gathering and mapping information
   - Analysing information
   - Generating solution
   - Submit final report and action plan

6. Within 20 days
   - Commissioner (with relevant stakeholders) undertakes a review of the final report and action plan and ensures it meets requirements for a robust investigation (see Appendix 8). Feedback given to provider (*calendar days)
   - Commissioner closes investigation and confirms timescales/mechanism for monitoring the action plan where actions/improvements are still being implemented.

7. Ongoing

Support and involve those affected (including patients, victims and their families and staff)
Opportunities for feedback and learning identified and information shared
APPENDIX C

Overview of the investigation process

This schematic provides a brief overview of a systems investigation for investigating serious incidents in the NHS. It requires a ‘questioning attitude that never accepts the first response’, and uses recognised tools and techniques to identify:

- The problems (the what?) including lapses in care/acts/omissions; and
- The contributory factors that led to the problems (the how?) taking into account the environmental and human factors; and
- The fundamental issues/root cause (the why?) that need to be addressed.

1 The investigation toolkit which can be accessed from [http://www.nrli.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/](http://www.nrli.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/) provides a wealth of tools, techniques and resources to support each stage of the investigation.
# Level of investigation for SIs

Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (currently referred to as RCA investigation). Within the NHS, most serious incidents are investigated internally using a comprehensive investigation approach. Resources to support systems-based investigation in the NHS are available online.

<table>
<thead>
<tr>
<th>Level</th>
<th>Application</th>
<th>Product/ outcome</th>
<th>Owner</th>
<th>Timescale for completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Concise internal investigation</td>
<td>Suited to less complex incidents which can be managed by individuals or a small group at a local level</td>
<td>Concise/ compact investigation report which includes the essentials of a credible investigation</td>
<td>Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Level 2</td>
<td>Comprehensive internal investigation</td>
<td>Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable</td>
<td>Comprehensive investigation report including all elements of a credible investigation</td>
<td>Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>Independent investigation</td>
<td>Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/capability of the available individuals and/or number of organisations involved</td>
<td>Comprehensive investigation report including all elements of a credible investigation</td>
<td>The investigator and all members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.</td>
</tr>
</tbody>
</table>

National reporting templates should be used unless agreed that adaptions are required. National templates will be reviewed on a continuous basis. Recommendations to inform changes should be sent to england.RCAinvestigation@nhs.net
Appendix D

Please note:
The 72 hour review is an internal process designed to capture early information relating to a potentially serious incident in order to inform decision making about further management. The information is based on what has been identified immediately after the incident and prior to any investigation. It is therefore not a comprehensive record of events and may contain information which later turns out to be incomplete or inaccurate. Whilst not routinely shared with partners outside the Trust it may on request be provided.

<table>
<thead>
<tr>
<th>Incident Immediate Review (72 hour)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part A for uploading to STEIS if applicable (anonymised)</td>
</tr>
<tr>
<td>Datix reference: DW number</td>
</tr>
<tr>
<td>Title of Incident:</td>
</tr>
<tr>
<td>Date of review:</td>
</tr>
<tr>
<td>Division: In which Division/CBU did the incident happen?</td>
</tr>
<tr>
<td>Exact Ward/Location: In which area or location of the hospital did the incident happen? e.g. x ward, x clinic or department</td>
</tr>
<tr>
<td>Specialty: In which specialty did the incident happen?</td>
</tr>
<tr>
<td>Incident date &amp; Time:</td>
</tr>
<tr>
<td>Degree of harm: No Harm/ Minimal / Moderate / Permanent/ Death</td>
</tr>
<tr>
<td>Agreed grade of incident investigation:</td>
</tr>
<tr>
<td>Report completed by (name and title)</td>
</tr>
<tr>
<td>Present at review meeting</td>
</tr>
</tbody>
</table>

**Brief summary of incident**

**Immediate Actions taken or to be taken to mitigate any further risk**
Core Investigation Team Agreed:

Lead investigator:

Supported by:

Terms of reference

Any additions to standard TOR?:

The aims of the incident investigation are:

- To identify and describe the course of events leading to the incident by:
  1. reviewing the patient’s medical records
  2. reviewing staff statements and interviewing the clinical staff involved as appropriate
- To identify care and service delivery problems which may have contributed to the incident.
- To undertake root cause analysis to identify the root causes and contributory factors leading to the incident.
- To evaluate practice against local and any national guidance or standards of good practice using change analysis.
- To identify potential ways in which systems and processes currently followed could be improved
- To make recommendations to reduce the risk of similar incidents occurring in the future
### KEY ACTIONS - CHECKLIST

<table>
<thead>
<tr>
<th>TASK</th>
<th>DATE</th>
<th>BY</th>
<th>COMMENTS/NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Datix Incident form completed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have the patient's notes been secured?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have statements been requested from staff?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(via Trust statement template)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Being open/duty of candour</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>This must be Followed For All SI's</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Being open/duty of candour lead – name</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Patient's Consultant or Ward Sister/Matron)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient/Family Liaison Lead – name</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(This person will be the point of contact</td>
<td></td>
<td></td>
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<tr>
<td>for the patient whilst the investigation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>is in progress).</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Patient/NOK informed and documented?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has patient/NOK been</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) informed of realistic timeline for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>completion of investigation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) asked if have any questions for the</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>investigation (DOC lead?)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a complaint linked to this</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient or incident?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Support for staff</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are nursing staff being supported – how</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and by whom? (Name)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are any junior doctors involved in the</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>incident?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other doctors/dentists involved?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Being</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>supported – by whom?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other staff involved?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Being supported – by whom?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a safeguarding alert been considered or raised?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Details of any other organisations identified and informed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Police/Media Interest?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For deaths – has the death been referred to the Coroner?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX E
INCIDENTS REPORTABLE TO THE HEALTH AND SAFETY EXECUTIVE UNDER THE REPORTING OF INJURIES, DISEASES AND DANGEROUS OCCURRENCES REGULATIONS (RIDDOR)

RIDDOR REPORTABLE INCIDENTS

Incidents are reportable to the HSE if they arise “out of or in connection with work” and are:

a) Accidents which result in an employee or a self-employed person dying, suffering a major injury or being absent from work or unable to do normal work for more than seven consecutive days;

b) Accidents which result in a person at work suffering an injury and being taken to a hospital for treatment or if the accident happens at a hospital, suffering a major injury;

c) An employee suffering one of the specified work related diseases;

d) One of the specified “dangerous occurrences” (this may not necessarily result in an injury but has the potential to do significant harm).

The definition of “Accident” include acts of physical violence to staff.

Accidents arising directly from the conduct of an operation, examination or other medical treatment by or under the supervision of a doctor or dentist are not reportable under RIDDOR.

Fatal accidents and those resulting in major injuries should be notified to the HSE without delay. This initial report must then be followed up within 15 days with a formal written report. The approved form F2508 must be used for this purpose. The Health and Safety Advisor is responsible for reporting all RIDDOR incidents to the HSE.

Where an employee suffers a work related accident and is, as a result, away from work, or unable to do their normal work for more than seven days (including non work days) the incident is reportable to the HSE.

Reportable specified injuries include:

- fractures, other than to fingers, thumbs and toes
- amputations
- any injury likely to lead to permanent loss of sight or reduction in sight
- any crush injury to the head or torso causing damage to the brain or internal organs
- serious burns (including scalding) which:
  - covers more than 10% of the body
  - causes significant damage to the eyes, respiratory system or other vital organs
- any scalping requiring hospital treatment
- any loss of consciousness caused by head injury or asphyxia
- any other injury arising from working in an enclosed space which:
Accident/Incident & Patient Safety Incident Reporting
Policy Including Serious Incidents Requiring Investigation

Royal Marsden NHS Foundation Trust Policy

Accident/Incident & Patient Safety Incident Reporting
Policy Including Serious Incidents Requiring Investigation

Royal Marsden NHS Foundation Trust Policy

Occupational Diseases

Examples of notifiable occupational diseases include:-

- some skin diseases such as occupational dermatitis
- occupational asthma or respiratory sensitisation
- work acquired infections such as hepatitis and tetanus
- any other infection readily attributable to work with biological agents; exposure to blood or bodily fluids or any potentially infective material

The Occupational Health Department are responsible for reporting all notifiable Occupational Diseases to the Health and Safety Executive.

Dangerous Occurrences

Dangerous occurrences are events which do not necessarily result in a reportable injury, but have the potential to do significant harm. Examples of reportable dangerous occurrences include:-

- collapse, overturning or failure of load bearing parts of lifts and lifting equipment e.g. patient hoists
- accidental release of a biological agent likely to cause severe human illness
- accidental release of any substance which may damage health e.g. mercury spillage, Cytotoxic drug spillage
- electrical short circuit or overload causing fire or explosion

Needlestick Injuries

Needlestick injuries are only reportable dangerous occurrences where they involve the release of blood or other material known to be infected with hazardous biological agents or hazardous substances.

A needlestick injury to a healthcare worker from a needle known to contain Hepatitis B positive blood would be reportable.
APPENDIX F

MEDICAL DEVICE ADVERSE INCIDENTS REPORTABLE TO THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

The Department of Health and NHS Executive require all healthcare organisations to have in place a system to ensure the prompt reporting of adverse incidents related to medical devices to the Medicines and healthcare products regulatory agency.

Incidents should be reported immediately following the incident. Serious cases should be telephoned directly to the MHRA and in all cases, a written report should be submitted.

The coordinator for the Trust is the Head of Risk Management and all reports should be forwarded to this person after notification to the MHRA. MHRA incident reports and investigations will be regularly reviewed by the Trust's Medical Devices Committee and as appropriate, reports submitted to the Integrated Governance and Integrated Governance Committee.

Definitions of Adverse Incidents

An adverse incident involving a device should be reported to the MHRA if the incident had led to, or could have led to:

- a death
- life-threatening illness or injury
- deterioration in health
- temporary or permanent impairment of a body function or damage to a body structure
- the necessity for medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
- unreliable test results leading to inappropriate diagnosis or therapy, or,
- where an incident was such that, if it were to occur again, death or serious deterioration in the health of the patient might result.

The MHRA should also be informed of any other device related adverse incidents or minor faults, since they may take on a greater significance when aggregated with other similar events in demonstrating trends, or, may be indicators of inadequate quality assurance on the part of the manufacturer or supplier.

Adverse incidents in medical devices may arise due to shortcomings in:-

- the device itself
- instructions for use
- servicing and maintenance
- locally initiated modifications or adjustments
- user practices, including training
- management procedures
- the environment in which it is used or stored
- incorrect prescription
APPENDIX G

<table>
<thead>
<tr>
<th>Patient</th>
<th>Visitor</th>
<th>Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>c/o Royal Marsden</td>
<td></td>
</tr>
<tr>
<td>Date of incident</td>
<td>Provider RM</td>
<td></td>
</tr>
<tr>
<td>Division</td>
<td>Department</td>
<td></td>
</tr>
</tbody>
</table>

**Description of incident, complaint or claim**

**Findings from the incident investigation**

**Actual effect on patient / service**

**Involvement and support of patients and relatives**

**Requirements of the Duty of Candour**

**Chronology**

Separate document.

**Care and service delivery problems identified**

**Contributory factors identified**

**Root causes identified**

**Recommendations:**

<table>
<thead>
<tr>
<th>ACTION</th>
<th>PERSON RESPONSIBLE</th>
<th>TIMEFRAME</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**Date submitted to IGRM**

<table>
<thead>
<tr>
<th>Authoring Department:</th>
<th>Risk Management</th>
<th>Version Number:</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author Title:</td>
<td>Head of Risk Management</td>
<td>Published Date:</td>
<td>01/05/2019 16:37:57</td>
</tr>
<tr>
<td>Ratified By :</td>
<td>IGRM; NRRAC</td>
<td>Review Date:</td>
<td>01/05/2020 16:37:57</td>
</tr>
</tbody>
</table>
Linked Documents

Whistleblowing Policy and Procedure
Risk Management Policy
Investigation of Incidents, Complaints and Claims Policy
Being Open / Duty of Candour Policy
Mandatory Training Policy / Training Needs Analysis
Decontamination of Medical Devices
Challenging Behaviour, Violence and Aggression from Patients and Visitors - Policy and Procedure for the Management of
Blood-Borne Viruses: Prevention of Infection (Inoculation Injury (Needlestick) Procedures)
Major Incident Plan
Emergency Command and Control Room and Hotline Policy and Procedures
Stress Management Policy
Safeguarding Adults Policy and Procedures
Child Protection and Safeguarding Children Policy
Information Governance Policy and Procedure

References

National framework for reporting and learning from serious incidents requiring investigation (National Patient Safety Agency NPSA 2010)
Serious incident framework (NHS England May 2015)
Being open – Communicating patient safety incidents with patients and their carers (NPSA 2009)
Openness and honesty when things go wrong the professional duty of candour (NMC & GMC June 2015)
CQC Regulation 20 Duty of Candour (November 2014)
Hard Truths: the Journey to Putting Patients First (January 2014)
Francis Report (2013)
Never Events Framework (2015/16)
An organisation with memory (Department of Health 2000)
Health and Safety at Work Act (1974)
CQC Fundamental Standards (updated 2014)
Achieving Consensus in Pressure Ulcer Reporting (Tissue Viability Society 2012)
Report of the Mid Staffordshire NHS Foundation Trust Public Enquiry (February 2013)
Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) October 2013
Guidance for Serious Incident Notifications London Local education and Training Boards (LETBs) of Health Education England (April 2015)