Significant Events (SAE: Serious Adverse Event) Policy

Nominated Individual	Richard Drakeford
Registered Manager	Robin Page
Date Policy Completed	March 2025
Version no.	1.0
Previous Review Dates	3/26
Review Date	March 2027 (or when updates are required)
Applicable to	All staff and contractors
Policy Signed By	RICHARD DRAKEFORD

INTRODUCTION

Responding appropriately to incidents or circumstances that have caused or may cause harm to patients, staff, including contracted staff, or visitors is a key part of the way that RE-PAT LTD will continually improve the safety of the services that it provides.

An incident reporting, management and investigation process is essential to ensuring that RE-PAT LTD responds to and learns from incidents. This policy lays out the process which facilitates the recognition, management, and investigation of incidents in a way which enables learning and the minimisation of future harm or loss within the service.

This policy includes the principles of 'Being Open' and the 'Duty of Candour' (as per RE-PAT LTD Duty of Candour Policy), which ensures that effective communication with patients and/or their families/representatives is central to the incident management and investigation process.

This policy also recognises the importance of RE-PAT LTD supporting reflection and learning, rather than encouraging a 'blame culture'. By doing this, Re-Pat Ltd will promote patient safety and staff development.

POLICY STATEMENT

Providing safe, effective, high-quality patient care is the aim of all staff at RE-PAT LTD. Given the complexity and the associated pressures resulting in increased workload, it is inevitable that significant events (SE), patient safety incidents (PSI) and other incidents will occur.
For the purposes of this document, three categories of incidents have been described:

1. Significant event
2. Patient safety incident
3. Non-clinical incident

The rationale for this is to distinguish and simplify the relevance of incident reporting for all staff.
Re-Pat Ltd will record and review all significant events for audit and governance purposes. All staff will be aware of the process of reporting all types of incidents which occur.
This policy will outline the procedure for reporting SE, PSIs and incidents within RE-PAT LTD. This applies to reporting incidents from a patient safety perspective and also those that may compromise staff safety concerns.

PRINCIPLES

This policy will ensure Re-Pat Ltd's commitment to the safety of patients. By promoting a reporting culture, staff are encouraged to report SE, PSIs and incidents. This will foster learning and help to prevent the recurrence of similar incidents in the future.
This policy should be read in conjunction with the Duty of Candour Policy and Procedures, Safeguarding Policy, Incidents and Accidents Policy and Information Governance Policy.

This policy sets out RE-PAT LTD systems, processes, and expectations in relation to significant event reporting, to include the following:

- Process for reporting all incidents involving staff, patients, and others
- Process for ensuring communication is open, honest, occurs as soon possible and is well documented
- Process for reporting to external agencies
- Process for investigating incidents according to level of risk
- Support available to staff who are involved in or witness to a serious incident
- Process for involving and communicating with internal and external stakeholders to share lessons learnt
- Process by which the organisation ensures local and organisational learning and changes in practice resulting from individual incidents and aggregated analysis
- Process for the aggregated analysis of incidents, complaints, and claims
- Governance processes which maintain oversight of the actions taken, lessons learnt, shared and improvements made
- Training and knowledge requirements for staff.

Who the policy applies to

This document applies to all employees of Re-Pat Ltd and any other individuals performing functions in relation to the organisation, such as agency workers, locums, and contractors.

Why and how it applies

It is the responsibility of all staff to ensure that they recognise, respond to and take the necessary actions regarding SE, PSIs and incidents. Staff must operate in an open and transparent manner, acknowledging that mistakes happen and take the subsequent necessary actions to report all incidents, thereby further reducing the risk of recurrence and ensuring that a high level of patient care is consistently delivered.
Staff are required to share best practice as SE, PSIs and incidents can arise through positive actions.

Definitions
Definitions are taken from both the World Health Organisation (WHO) International Classification for Patient Safety and the Reporting and learning from patient safety incidents.pdf (rcgp.org.uk) (pp35).

Patient Safety
The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum which refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.

Serious Incident
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 that affect patients directly and include incidents that may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.
https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

Serious incidents are declared internally as soon as possible, and investigation reports are completed within 60 working days.
Serious incidents are adverse events, where the consequences to patients, staff, visitors or members of the public are so significant, or the potential for learning is so great, that a heightened level of response is justified, and they warrant using additional resources to mount a comprehensive response.
Serious incidents extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or the organisation's ability to deliver its essential activities.
There is no definitive list of events and incidents that constitute a serious incident, and all incidents must be considered individually, relying on the judgement of those involved to ensure they are investigated and managed at a consistent and appropriate level.

However serious incidents which must be declared include:

- Acts or omissions arising from RE-PAT LTD's activities that result in:
    - unexpected or avoidable death
    - unexpected or avoidable injury resulting in serious harm:

    a) The death of the patient, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition
    b) An impairment of the sensory, motor or intellectual functions of the patient which has lasted, or is likely to last, for a continuous period of at least 28 days
    c) Changes to the structure of the patient's body
    d) The patient experiencing prolonged pain or prolonged psychological harm (a continuous period of 28 days or more)
    e) The shortening of the life expectancy of the patient

    OR
    Requires treatment by a healthcare professional in order to prevent:

    (a) The death of the patient
    (b) Any injury to the patient which, if left untreated, would lead to one or more of the outcomes mentioned in the section above.

- Unexpected or avoidable injury that required transfer to hospital for further treatment in order to prevent death or serious harm

- 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, FGM, human trafficking and modern day slavery where

- RE-PAT LTD did not take appropriate action / intervention to safeguard against such abuse occurring, or
- Where abuse occurred during screening and diagnostic services provided by RE-PAT LTD.

Significant Event
Any unintended or unexpected event that could or did lead to harm of one or more patients and this includes incidents that did not cause harm but could have done or where the event should have been prevented

Never Events
Never events are serious incidents that are wholly preventable due to guidance or safety recommendations that provide strong systemic protective barriers being available at a national level and should have been implemented by RE-PAT LTD. They are defined as serious incidents although may not result in serious harm or death and include:

- Overdose of medication administered
- Actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals.

Near Misses
When an incident has been avoided but had the potential to cause harm or injury it may be appropriate to class a near miss as a serious incident. This may be either on RE-PAT LTD premises or to an individual carrying out RE-PAT LTD business, or involve:

- Damage or loss to RE-PAT LTD property,
- Damage or loss to RE-PAT LTD reputation,
- Damage or loss to RE-PAT LTD integrity.

Consideration to whether a near miss is a serious incident is based on that which may have given rise to possible harm:

- The likelihood of the incident occurring again if current systems / process remains unchanged, and
- The potential for serious harm to, or death of, staff, patients and visitors, and the risk to the organisation should the incident occur again.

Significant Event Analysis
A case-by-case analysis to encourage the whole healthcare team involved in a case or incident to have a supportive discussion. The aim is to use this as a process to allow reflection and learning from the incident and so improve care.

Care Quality Commission
The independent regulator of all health and social care services in England.

Information Commissioner's Office (ICO)
The Information Commissioner is the UK's independent regulator for Data Protection and Freedom of Information.

ROLES AND RESPONSIBILITIES

The Company Director is responsible for:

- Ensuring arrangements are in place to effectively manage and learn from incidents as part of the risk management approach
- Ensuring that an effective risk management system is in place within the organisation of which incident reporting forms one element
- Responsible for ensuring the review of all service related and clinical incidents, including near misses
- Ensure that incidents that are reportable to external authorities are reported correctly
- Critically analysing the incident for contributory factors to identify root causes and changes that may be required to policy and practice.

The Registered Manager is responsible for:

- Ensuring all action has been taken to ensure the safety of the situation and any persons involved
- Considering whether staff involved in the incident are able to continue work safely and effectively in the immediate aftermath of the incident.
- Ensuring that there are systems in place to monitor incidents, complaints, and concerns within RE-PAT LTD, and that incidents are investigated according to this policy.
- Ensuring that all staff within their sphere of responsibility are aware of this policy and associated procedures and that these are implemented effectively
- Facilitating learning from incidents, complaints, and concerns by ensuring that these are discussed within the team
- Escalating incidents as detailed in this policy including reporting correctly to external bodies as required
- Ensuring all relevant documentation is gathered, completed, and stored securely.
- Recording any interviews, findings from the investigation and any further follow up actions. Documents should be attached
- Investigation of the incident to establish what has happened and who, or what, has been affected. This investigation may involve reviewing case notes or interviews with staff etc
- Signing off the incident once a full investigation is complete.

When it is necessary to interview staff, management must ensure that interviews are:

- Undertaken away from the immediate place of work
- Last no more than thirty minutes
- Determine what happened
- Identify all contributory factors
- Conducted in a supportive manner, not judgemental nor confrontational.

If it becomes clear that a professional shortcoming has occurred, this should be allowed to emerge naturally from the conversation and should not be extracted by cross-examination.

Staff affected by or involved in an incident, complaint, or witness to an incident

There is a general requirement for employees:

- To take care of themselves whilst at work and not put patients, family members, volunteers, visitors, members of the public or colleagues at risk by any act or omission on their part
- To cooperate with their employer to enable their employer to comply with their statutory duties
- To bring to the notice of their line manager any workplace health and safety risks or incidents.

Following an incident, employees are specifically required to:

- Where possible, make the situation safe for themselves and others bearing in mind the retention of evidence and possible crime scene or scene of investigation
- Perform any treatment, or first aid, where competently trained to do so, following an incident
- Summon appropriate support, where able, following an incident
- Complete and submit an incident report form
- Provide a statement of events when requested.

SIGNIFICANT EVENT ANALYSIS

Rationale

Significant event analysis (SEA herein) at RE-PAT LTD is used to identify both good and poor practice. However, the overall aim of the process is to enable reflection and learning thereby enhancing the level of service offered to the patient population.

Involving the Team

SEA at RE-PAT LTD involves all members of the multidisciplinary team (MDT). Staff must acknowledge that SEAs are centred on whole-team learning and are not used to direct blame.

Aims of SEA

The aims of completing SEAs are to:

- Identify events in individual cases that have been critical and to improve the quality of patient care from the lessons learnt

- Instigate a culture of openness and reflective learning, not individual blame, or self-criticism

- Enable team building and support following stressful episodes

- Enable the identification of good as well as suboptimal practice

- Be a useful tool for team and individual continuing professional development, identifying group and individual learning needs

- Share learning between teams within other primary medical services where adverse events occur at the 'overlap' or in shared domains of clinical responsibility (such as 'out of hours', discharge from service, etc.).

What constitutes a SEA?
Examples of significant events can be very wide-ranging and can reflect good as well as poor practice and can include:

- Coping with a staffing crisis
- Complaints or compliments received by the practice
- Breaches of confidentiality
- A sudden unexpected death or hospitalisation of a patient
- Prescribing errors
- Important messages not relayed
- An unsent referral letter
- Wrong/incorrect treatment
- Drug interaction
- Delayed diagnosis
- Loss of care data
- Health and safety concerns or breach.

Benefits of significant Event Analysis
Undertaking a SEA will enable the practice team to:

- Reflect on the incident
- Undertake root cause analysis
- Discuss and implement preventative measures
- Enhance learning
- Demonstrate a culture of openness and transparency
- Improve patient care and experience.

A HEALTH AND SAFETY EVENT OR INCIDENT

Supporting Policies

At RE-PAT LTD we hold a library of policies and guidance documents that can support an incident or event that involves a health and safety event. Should there be such an incident, initial reference is to be made to the Health and Safety Policy and reported as per the RIDDOR requirements.

Other specific and supporting policies may also be required, such as:

- Accident and Incident Policy
- Fire Safety Policy
- First Aid Policy
- Safeguarding Policy
- Duty of Candour Policy

Other supporting documents could include:

- COSHH Policy
- Risk Assessments

ANALYSIS OF AN EVENT OF INCIDENT

Root cause analysis

Occasionally an incident requires a detailed root cause analysis investigation using an approved investigation methodology (root cause analysis), either due to the seriousness to the individual, an /or the organisation, and/or because of its potential for learning and reflection.
Root cause analysis (RCA) is defined as a collective term that describes a wide range of approaches, tools and techniques used to uncover the causes of problems. The need for a more detailed investigation will be determined by the nature, scale, and consequence of the incident.
When an incident is identified as being suitable for a root cause analysis investigation, the Registered Manager or Company Director will be responsible for this process.

How to Perform Root Cause Analysis (RCA)

RCA can be raised for an SI, SE, or PSI to understand why the incident occurred in the first place and, by doing so, identify areas for improvements that may prevent the incident from being repeated.

Repeatedly asking the question 'why?' (use five as a rule of thumb) can quickly identify the source of an issue or problem, allowing the focus of resources in the right areas.

An example of root cause analysis using five whys would be:

The Five Whys		
1	There was a delay in the patient receiving oxygen when suffering with a medical emergency	Why?
2	The oxygen was not readily available	Why?
3	The oxygen bottle was empty and had not been replaced	Why?

4	The patient was being tended to by a locum member of staff who did not know where the emergency equipment was located and no emergency equipment checks had taken place	Why?
5	The regular member of staff was absent through sickness and replacement staff had not been tasked to undertake the emergency checks	Why?

The source of the problem in this case quickly becomes apparent. At RE-PAT LTD, root cause analysis is routinely carried out to identify the cause of all incidents.

Auditing, Reflection and Learning following an Event or Incident

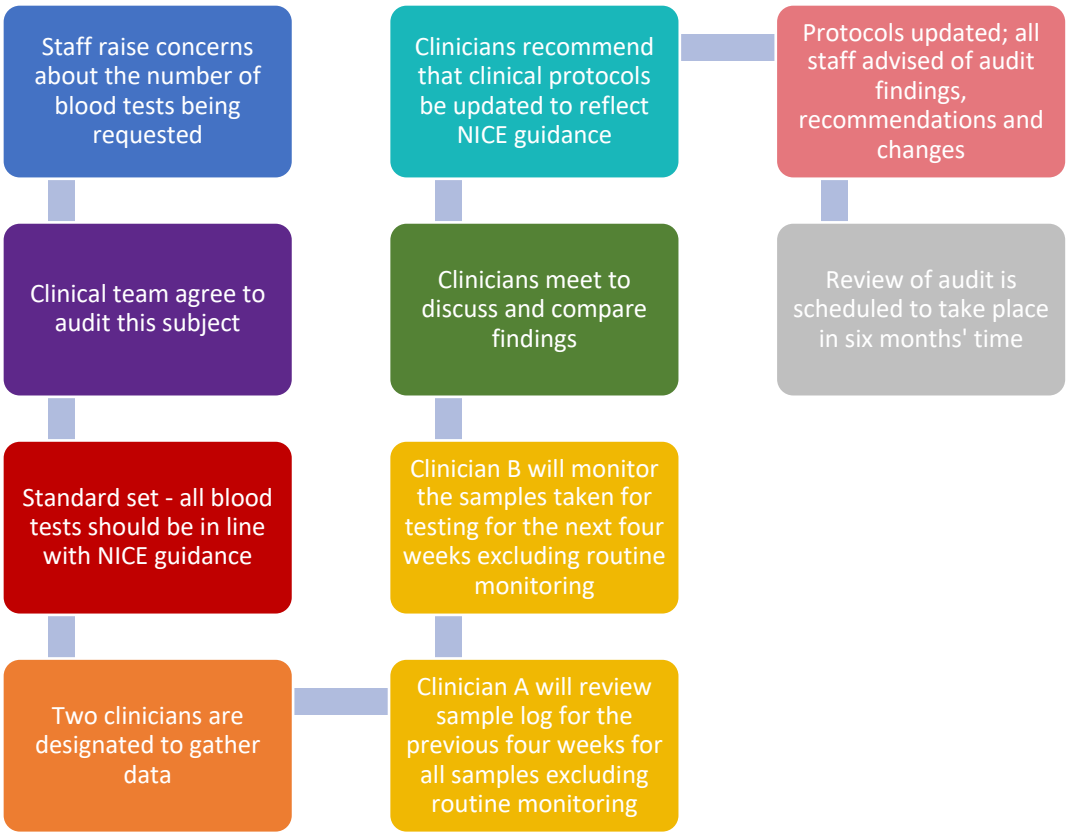
Following any incident or event, part of the management response will be to instigate an investigation that includes audit. The purpose of having an audit is to:

- Identify and highlight evidence-based practice
- Identify areas for improvement and enhance patient safety
- Provide data that can be used to review the effectiveness of service delivery
- Enhance multidisciplinary team communication
- Improve cross-functional working within the practice

Throughout the audit cycle, all audits will be discussed at the various practice meetings on a quarterly basis, thereby ensuring that all staff are aware of ongoing progress as well as having the opportunity to:

- Discuss the findings of audits
- Learn from any outcome or best practice considerations
- Consider how the changes will be implemented across the organisation.

An example of how the audit process works:



Trend Analysis

The Registered Manager and Company Director are responsible for ensuring that incident patterns and trends are analysed at RE-PAT LTD and operational level and that the findings are discussed during staff meetings.

SIGNIFICANT EVENT REPORTING

Reporting Advice

RE-PAT LTD has a legal duty to report certain types of incidents externally. These include serious incidents, never events and certain types of accidents or injuries. All staff are permitted to raise and complete a SEA. However, to enable learning and prevent similar repeat occurrences, it is requested that staff advise the practice manager of their intention to complete a SEA.
Patient and staff personal identifiable information is not required when completing a SEA and staff should refer to the individuals involved as Patient A, Staff member A, etc.
A safety incident can involve a patient or a staff member. Should an accident occur, this policy is to be read in conjunction with rother relevant policies, including the Accident and Incident Policy and Duty of Candour Policy.

Which incidents are reportable?
Clinical and non-clinical patient safety incidents should be reported in cases of patient harm or where there was the potential for harm to have been caused. This includes near misses and the reporting of positive outcomes, i.e. an incident was prevented as a result of effective processes/protocols.

Regulation 18 specifies events or occurrences that affect the health, safety and welfare of people who use services that must be notified to CQC. These include:

- A serious injury to a service user
- Abuse or allegations of abuse
- Incidents that are reported to or investigated by the police
- Any event that stops or may stop the registered person from running the service safely and properly.

The full list is available here.

The CQC only needs to be informed of an applicable incident if it:

- Took place whilst a regulated activity was being provided

- May have been the result of the regulated activity or how it was provided.

Organisations are legally obliged to notify certain changes, events and incidents that affect their service or the people that use it under Care Quality Commission (Registration) Regulations Regulation 18 (2). Incidents include all those that affect the health, safety and welfare of people who use the organisation's services. Serious injury to any person using the service is to be reported using the statutory notification form and submitted to HSCA_notifications@cqc.org.uk or via the Provider Portal.

In the event of a requirement to notify a patient death under Regulations 16 and 20, including as a result of confirmed or suspected coronavirus, a different notification form is to be completed and submitted to: HSCA_notifications@cqc.org.uk or via the Provider Portal.

The police must be informed of any death directly because of an incident, or any major injury as a result of a Road Traffic Collision or assault whilst on company business. Copies of any available details should be sent to the police and a record should be kept as part of the accidents and incident log, of the police officer's name together with a summary of the discussion.

The Health and Safety Executive (HSE) must be informed of Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) reportable incidents as per RE-PAT LTD's Health and Safety Policy.

RE-PAT LTD insurer should also be informed of all RIDDOR reportable incidents, deaths following an incident, cases of alleged abuse or neglect, incidents involving a head injury or incidents where the threat of a claim has been made.

Categories of Incidents to be Reported
There are a number of events and incidents that need to be recorded and/or reported and this includes the following:

- Significant events (SE)
- Patient safety incidents (PSI)
- Non-clinical incidents including:
  - Vehicle or equipment issues
  - Health and safety issues
  - Data breaches

Benefits of Incident Reporting
Reporting upon an incident that compromised patient safety will enable this organisation to:

- Reflect on the incident
- Discuss and implement preventative measures
- Enhance learning
- Demonstrate a culture of openness and transparency
- Meets requirements in-line with CQC Regulations 2009

TOOLS FOR REPORTING EVENTS AND INCIDENTS

NRLS enables patient safety incident reports to be submitted to a national database. This provides the opportunity to ensure that the learning gained from the experience of a patient in one part of the country is used to reduce the risk of something similar occurring elsewhere.

At RE-PAT LTD patient safety incidents are reported using the SEA Toolkit.

1. INVESTIGATING INCIDENTS

The incident report is the first part of the process that enables RE-PAT LTD to identify what caused the incident to happen. Identifying the underlying cause of an incident is important to enable the organisation to learn and increase the likelihood that an incident will not happen again.

The cause of an incident may not be immediately apparent, and all contributory factors must be considered for example

- Communication
- Working conditions
- Education and training

- Equipment and resources
- Individuals
- Team and social considerations
- Task
- Process and procedure.

Witness Statements

Witness statements are not routinely required but may be requested to form part of an investigation and used in legal proceedings. They may be prepared with assistance from managers or Trade Union Representatives. These are stored with the incident report in RE-PAT LTD Accident and Incident Reporting log.

When an incident involves a former employee, the former employee may be requested to complete a witness statement to assist in an investigation.

2. MONITORING AND LEARNING FROM INCIDENTS

Incidents are monitored to ensure appropriate action has been taken and completed and any learning is shared within the team and with external agencies, as necessary.

Recording information about things that could have or did affect the safety of patients, or things that have gone well, will support learning and safety improvement of the practice.

Management will have access, can review and update event records if given permission to edit, and undertake governance activities to support local patient safety response and improvement.

3. CONFIDENTIALITY AND STORAGE

Incident reports are handled and processed on a confidential basis and are subject to RE-PAT LTD's protocols regarding confidentiality and data protection.

Information may need to be transmitted to other individuals or agencies as part of the subsequent investigation process, but this is always undertaken on a need-to-know basis. The names of individuals will always be omitted from summary reports and statistics produced for managerial and operational purposes. Summary reports of incidents will be anonymised.

When external professionals, contractors or organisations are involved in an incident this will be reported to the most appropriate person within the other organisation, ensuring confidentiality and protection of data.

In cases where litigation ensues, the incident report and associated information may need to be submitted as formal evidence in court.

4. INFORMATION COMMISSIONER'S OFFICE

The Information Commissioner is the UK's independent regulator for Data Protection and Freedom of Information with key responsibilities under the Data Protection Act 2018 (DPA) and Freedom of Information Act 2000 (FOIA) as well as various other acts.

Further information on the ICO can be found at ico.org.uk.

RE-PAT LTD follows good practice in relation to data protection in order to ensure there is public trust in, and support for, the use of patient data.

UK data protection governance is set out in the DPA 2018 and the UK GDPR.

In relation to this policy, it is likely that most incidents will involve a data breach. According to the ICO, the strict definition of a personal data breach is:

'A breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed in connection with the provision of a public electronic communications service'.

This will usually mean that someone other than the data controller has had unauthorised access to personal data for which RE-PAT LTD is responsible. Furthermore, it might also include unauthorised access within RE-PAT LTD as an employee accidentally altering, using inappropriately, or deleting personal data.

You must notify the ICO within 24 hours of becoming aware of the essential facts of the breach.

This notification must include at least:

- Name and contact details
- The date and time of the breach (or an estimate)
- Basic information about the type of breach
- Basic information about the personal data concerned

Further information on data breaches can be sought from ICO

An incident reporting flow chart can be found on page 19 to assist staff at RE-PAT LTD to identify incidents that require prompt and appropriate reporting.

5. AIDE

An incident reporting flow chart can be found on the diagram below to assist staff at RE-PAT LTD to identify incidents that require prompt and appropriate reporting.

6. RECORDING SI, SE, PSI'S

Template Usage
At RE-PAT LTD all staff must use RE-PAT LTD template form for reporting of SEA's.
Organisation Lead

The lead for SIs, SEs and PSIs at RE-PAT LTD is the Registered Manager and they will be able to provide guidance to individuals should they have any queries or concerns relating to any SE or incident.

Team Meetings
SEs, PSIs and SIs are a daily occurrence across the NHS. By demonstrating a culture of accurate reporting, this will illustrate a whole-team approach to maintaining a safe and effective environment and the drive to deliver an excellent standard of patient care at RE-PAT LTD.
At RE-PAT LTD, team meetings to discuss SEs and incidents will be held monthly and all staff will be invited to attend.

CONCERNS AND COMPLAINTS

A concern or complaint is any expression of dissatisfaction. Concerns and complaints should be recorded as an incident. All records relating to the concern or complaint and the outcome will be held by the Registered Manager. Please refer to RE-PAT LTD's Complaints Policy and Procedure.

TRAINING

All staff should receive guidance in how to complete RE-PAT LTD's accident and Incident reporting log.
Management will be trained in how to manage, investigate, grade, monitor and sign off incidents.
RE-PAT LTD will provide guidance and support to help those to whom it applies to understand their rights and responsibilities under this policy. Additional support will be provided to the registered manager to enable them to deal more effectively with matters arising from this policy.

EQUALITY AND DIVERSITY

RE-PAT LTD will ensure that the contents of this document are applied in a fair and reasonable manner that does not discriminate on the grounds of any protected characteristic as defined by the Equality Act 2010.

RELATED POLICIES AND PROCEDURES

Quality Governance and Risk Policy

Complaints Policy

Duty of Candour Policy

Information Governance Policy

Record Keeping Policy

Equality and Diversity Policy

Medical Emergency Policy

Medication Management Policy

Safeguarding Policy

RELEVANT GUIDELINES AND LEGISLATION

Health and Safety at Work Act 1974

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

HSE Health Service Information Sheet No 1 – Reporting injuries, diseases and dangerous occurrences in health and social care. Guidance for employers (10/2013)

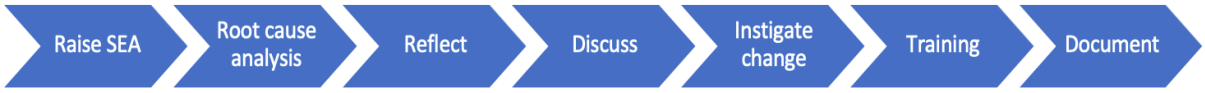
HSE HSG: Reducing Error and Influencing Behaviour

National Patient Safety Alerts - https://www.england.nhs.uk/patient-safety/patient-safety-alerts/

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013

Appendix 1 Easy Guide to Reporting Events and Incidents

1. Clinical Incident / SUI – No harm



2. Clinical Incident / SUI – Near miss or harm caused

3. Non-clinical incident – Non data

4. Non-clinical incident – Data

Appendix 2 Incident Reporting Form – Re-Pat Ltd

Instructions for Completion:

Complete all relevant sections
Submit to the Registered Manager immediately upon completion
Ensure the form is stored securely as per confidentiality and data protection guidelines

Table of Contents

Submission Details

Form Submitted by:
Name: [Insert name]
Role: [Insert role]

Date: [Insert date]

Submitted to Registered Manager:
Name: [Insert name]
Date Received: [Insert date]
Date Section 8 (outcome) completed

Section 1: Event Details

Date of Incident:[Insert date]

Time of Incident:[Insert time]

Location of Incident:[Insert location]

Type of Incident:(Select all that apply)

- ☐ Significant Event (SE)
- ☐ Patient Safety Incident (PSI)
- ☐ Non-Clinical Incident (e.g., data breach, building issue, health and safety)
- ☐ Near Miss
- ☐ Other (Specify): _____

Section 2: Individuals Involved

Person Reporting the Incident:
- Name: [Insert name]

- Job Title: [Insert title]

- Contact Details: [Insert contact details]

- Date of Report: [Insert date]

Individuals Involved in Incident:
(Use anonymized identifiers, such as Patient A, Doctor A)

- Name(s):

- Role(s):

- Involvement: [Brief description of roles]

Section 3: Description of the Incident

Description of the Incident:
(Provide a detailed account of what occurred, including any relevant background or context. Attach additional sheets if necessary.)

[Insert description]

What Happened?(Include the sequence of events)
[Insert description]

Impact on Individuals:
(Describe any harm or potential harm, injuries, or negative outcomes that occurred.)
[Insert description]

Was Immediate Action Taken?
☐ Yes
☐ No
If yes, please specify:
[Describe any immediate action]

Investigation, Learning and Outcome

Section 4: Investigation and Analysis

Root Cause Analysis Conducted:
☐ Yes
☐ No
If yes, briefly outline findings:
[Describe findings]

Were the 'Five Whys' Method or another analysis technique used?
[Describe]

Section 5: Duty of Candour

Was the Duty of Candour Invoked?
☐ Yes
☐ No

If yes, describe communication with patient/family/advocates:
[Describe communication]

Section 6: Risk Assessment

Risk Level:(Select one)
☐ Low
☐ Moderate
☐ High
☐ Critical

Potential for Recurrence:
[Insert likelihood of recurrence]

Has the risk been added to the Risk Register? Y/N

Section 7: Actions and Recommendations

Immediate Actions Taken:
[Describe immediate steps taken]

Preventive Measures/Recommendations:
[Describe steps to prevent future incidents]

Were any Policies or Procedures Revised?
☐ Yes
☐ No
If yes, specify:
[Describe changes]

Section 8: Outcome

Outcome of Incident:
[Provide details of any outcomes, including patient status, team decisions, and resolutions.]

Was a Serious Incident (SI) Declared?
☐ Yes
☐ No

Outcome Logged by Registered Manager:
Date: [Insert date]
Comments: [Insert final outcome and review details]

Company Registered in England
13918654