Significant Events Policy

SpiroSense - Independent Respiratory Diagnostics
Person responsible - Catherine Bridges
Date created - 04/02/26
Review date - 03/02/27

Purpose

SpiroSense is committed to delivering safe, high-quality services. This policy provides a clear framework for reporting, recording, and learning from **significant events**, near misses, or incidents that could affect the **safety, welfare, or rights of service users or staff**.

It supports compliance with:

- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 – **Regulation 17: Good Governance**
- Care Quality Commission guidance on incident reporting
- Duty of candour requirements

Scope

This policy applies to:

- All clinical and non-clinical incidents at SpiroSense
- Near misses, errors, or equipment malfunctions
- Any event that could compromise patient safety, data security, or service quality

It applies to:

- The Registered Manager / Clinical Lead (sole practitioner)
- Any contractors or temporary staff who may be involved in service delivery

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Definition of a Significant Event

A **significant event** is any occurrence that:

- Causes harm to a patient, staff member, or visitor
- Has the potential to cause harm (near miss)
- Breaches regulatory or professional standards
- Poses a risk to the service's operational or clinical effectiveness

Examples include:

- Equipment failure during a diagnostic test (e.g., spirometer malfunction)
- Adverse reaction during testing
- Safeguarding concern or disclosure
- Data breach or loss of patient records
- Complaints indicating potential harm or risk

Reporting a Significant Event

Immediate Action

- Ensure the **safety of the patient and staff** first
- Call emergency services if required (999)
- Contain the incident if possible (e.g., stop testing, isolate affected equipment)

Reporting Process

1. **Recognise the event** – identify it as a significant event or near miss
2. **Document factual details immediately** – what happened, when, who was involved, actions taken
3. **Assess immediate risk** – to patient, staff, or service operations
4. **Notify relevant parties** – for SpiroSense, this is usually the Registered Manager (self) and, if necessary, external authorities
5. **Record the incident** – complete the **Significant Event Log**

Investigation and Follow-Up

- Investigate the cause of the event as soon as possible
- Determine contributing factors and whether it was preventable
- Identify actions to prevent recurrence
- Document findings and any learning points
- Implement changes to policies, procedures, or training as required

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Learning and Improvement

- All significant events are **reviewed to identify trends and learning opportunities**
- Changes may include:
    - Updating equipment maintenance schedules

    - Modifying IPC or clinical procedures
    - Staff training updates (if applicable)
- Learning is shared appropriately with any staff or contractors

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Duty of Candour

- Where the incident involves patient harm, SpiroSense follows **duty of candour principles**:
    - Inform the patient about the incident in a timely and transparent manner
    - Provide an apology and explanation
    - Outline steps taken to prevent recurrence

Record Keeping

- All significant events are recorded factually in a **Significant Event Log**
- Logs include:
    - Date and time of incident
    - Description of the event
    - Persons involved
    - Immediate actions taken
    - Investigation findings and outcomes
    - Lessons learned and changes implemented
- Records are stored securely and retained for **at least 8 years** in line with data protection legislation

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External Reporting

SpiroSense will report externally where required:

- **Care Quality Commission (CQC)** – if incident meets statutory reporting thresholds https://www.cqc.org.uk/guidance-providers/reporting-incidents
- **Professional regulator** – if required (e.g., GMC, HCPC)
- **Local Authority Safeguarding Team** – if the incident involves a safeguarding concern

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Governance

- The Registered Manager reviews all significant events to ensure:
    - Compliance with regulatory requirements
    - Lessons learned are implemented
    - Policies and procedures remain effective
- This policy is reviewed **annually** or sooner if guidance or legislation changes

References / Guidance

- Health and Social Care Act 2008: Regulated Activities Regulations 2014 – **Regulation 17**
  https://www.legislation.gov.uk/uksi/2014/2936/regulation/17/made
- CQC – Guidance on Reporting Incidents
  https://www.cqc.org.uk/guidance-providers/reporting-incidents
- Duty of Candour Guidance
  https://www.cqc.org.uk/guidance-providers/regulations/duty-candour

Policy Review

This policy is reviewed annually or following changes to legislation or guidance. Legislation and guidance links are checked and updated as part of the annual policy review.

Last review date: 04/02/26
Next review date: 03/02/27