Southern Ultrasound Ltd.

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Incident Reporting Policy – Including Serious Incidents.

VERSION CONTROL

V1	21/08/18	Policy creation
V2	09/05/19	Amended to better incorporate FHNHSFT procedures

POLICY STATEMENT

Southern Ultrasound is committed to making safety a priority and to doing its reasonable best to prevent injury, ill-health and harm to patients, staff & visitors, and to prevent loss & damage to Company & Clients assets & reputation and to prevent breaches of patient confidentiality.

Southern Ultrasound recognises that although serious incidents in health & social care are relatively uncommon, from time to time things can and do go wrong. When adverse incidents do occur, the Company has a responsibility to ensure that there are systematic measures in place for safeguarding people, property, resources and reputation. This includes responsibility to learn from these incidents in order to minimise the risk of them happening again.

To achieve this, the Company will have in place a robust system of identifying, investigating and learning from all types of incidents. Learning from the identification of root causes of incidents will provide a key lever for change & improvement in relation to safety.

The reporting and management of incidents is a critical tool in assisting the organisation to effectively manage risk. The reporting of incidents and near misses provides valuable data which can help improve safety, prevent the recurrence of incidents and facilitate wider learning.

This policy covers the reporting and investigation processes for all clinical and non-clinical incidents including Serious Incidents (SIs), near misses and hazards and applies to incidents involving service users, visitors or carers, the public, employees or business of the Company; in line with **NHS Improvement's Serious Incident Framework - March 2015.** *A copy of the above framework is available for all staff in the* ***Incident*** *sub-folder of the* ***Information For Staff and Contractors*** *section of the Company's on-line* ***Quality Assurance system***

This policy includes the principles of "being open" and "duty of candour" – applicable to all staff. Where incidents occur, we need to evidence openness, honesty and transparency so that early warning systems can work. Expectations of the duty of candour following the Francis report and the contractual duty as described in the NHS Standard Contract 2013/14 – 18/19 include ensuring that any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

This policy covers both Clinical and Non-Clinical Incidents, Mild to Serious in nature, including Actual, Potential and Near-Miss incidents. Only by investigating and acting on all such situations, can the company provide maximum security for patients, staff, data and company processes. Whilst most of the policy applies Company-wide, certain sections are directly applicable to our work with Frimley Health NHS Foundation Trust [FHNHSFT] with procedures that dovetail into the FHNFT policies and procedures. These sections are shown in BLUE text.

PURPOSE

Southern Ultrasound recognises that incidents may occur because of problems with systems, processes or individuals. It is the Company policy to promote a positive approach to incident reporting throughout the organisation. Staff are encouraged, and will be supported, to be open and honest about events and issues that have or could cause damage to people, property or the organisation. The Company operates an open and fair blame culture and will accept liability for the actions of staff as long as they were carrying out their duties in accordance with Company policy, their professional standards, information, instruction, training and supervision they had received. Any disciplinary action will only be considered in accordance with the Disciplinary Policy.

The Company wishes to learn lessons and improve through the investigation of incidents. It is imperative that the Company incident reporting system is used as a proactive mechanism for risk management.

The objectives of the policy are consistent with the former National Patient Safety Agency guidance on the Seven Steps to Patient Safety (2009) which are:

- Step 1 Build a safety culture
- Step 2 Lead and support your staff
- Step 3 Integrate your risk management activity
- Step 4 Promote reporting
- Step 5 Involve and communicate with patients and the public
- Step 6 Learn and share safety lessons
- Step 7 Implement solutions to prevent harm

NOTE: Although the NSPA has now been amalgamated into NHS Improvement, these basic safety steps remain very much applicable.

SCOPE

This Policy applies to all Company staff and contractors working on Trust or Client premises, as well as staff with in Company Offices or on Company Business - including staff on interim or honorary contract and volunteers. It covers all types of incidents. Sections in blue text are applicable to issues specifically in relation to FHNHSFT.

RESPONSIBILITIES OF STAFF & OFFICERS

Directors

The Director(s) of Southern Ultrasound have ultimate responsibility of ensuring that serious incidents are reported through the correct channels, in accordance with legal and contract requirements.

The Director(s) have accountability for ensuring there is a sound system of effective risk management is provided within the Company including ensuring that all incidents are reported and investigated and all Serious Incidents (SI) have been fully investigated via Root Cause Analysis and appropriate actions to prevent reoccurrence have been taken and that learning and improvement from Serious Incidents is being shared and improvements made as a result. Where the Director(s) lack sufficient expertise to fully investigate an incident, external experts must be sought.

Senior Managers

Senior Managers and Governance leads are often the first Officers of the Company to be made aware of any incident, and are required to bring the matter to the attention of company Director(s) at the earliest possible opportunity.

Where patient or staff safety is at risk, they are also authorised to take whatever steps they deem necessary, in association with local management, to minimise the situation and prevent reoccurrence.

Health & Safety Lead

RIDDOR - The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) as amended 2013 require a range of incidents to be reported to the Health & Safety Executive (HSE) where an employee is absent from the workplace or unable to carry out their normal duties for more than 7 consecutive days after a workplace injury and any Trust activity or work that adversely impacts on the health and well-being of a patient or visitor to the Trust. Reportable incidents may include the following:

- fractures; amputations;
- an injury likely to cause loss of sight;
- any crush injury to the head or torso causing damage to the brain or internal organ;
- any burn injury (including scalding) which covers more than 10% of the whole body's total surface area; any loss of consciousness caused by head injury or asphyxia
- Staff, of patient affected by dermatitis or develops an allergy to latex
- Visitor slipping on water on the floor in corridor and breaking an arm or leg

The Health & Safety Lead will, when required, complete RIDDOR forms and send them to the Health & Safety Executive within 15 days. The Health and Safety Lead will offer assistance and training regarding the Company's RIDDOR responsibilities. The Health and Safety Lead will also monitor the reporting of all Health and Safety related incidents, including circulation of Health and Safety incident statistics. In addition they will liaise with the HSE in respect of any requested site inspections.

Information Governance Manager

The Information Governance Lead will oversee the reporting of information governance incidents, be involved with agreeing the terms of reference for investigations and provide the expertise to the management, investigation and closure of all Information Governance SIRI (Serious Incident Requiring Investigation). They will also be responsible for involving the Caldicott Guardian and Senior Information Risk Officer (SIRO) where appropriate.

All staff; inc: contractors, volunteers, students & others

Staff Responsibilities: All staff have a duty to report an accident, incident or near miss to their manager as soon as is reasonably practicable after the incident. This is an integral aspect of a healthcare professional's Duty of Candour, requiring them to open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress

Staff members are held responsible for the reporting of all incidents to which they are aware of, whether involving themselves, patients, visitors or other staff.

The report will be made using the Company's Incident Reporting system: See: Appendix 1.

Contractors, Volunteers, students, work experience placements etc: shall report any incident to a member of staff who will then have the responsibility for reporting. The person identifying the incident will be responsible for taking any required immediate action, giving a witness statement and taking part in any investigation as required by the investigating officer.

Where a person identifying the incident is unable to report the incident, i.e. as a result of injuries sustained, unconsciousness etc., the responsibility for reporting will rest with any staff initially made aware of the incident.

All staff (including temporary staff) are responsible for reading and adhering to this policy.

Staff must report incidents, including near-misses in accordance with this policy and fully co-operate with any investigations. They must ensure the patient/service user involved is aware of the incident consequences and actions taken, in line with the Being Open Policy.

Staff reporting the incidents should include their name as reporter and the area in which they work. However, there is scope to report incidents and concerns anonymously although this may make it more challenging to investigate.

DEFINITIONS

Adverse event / Accident: An incident that led to actual harm, loss or damage. (See adverse incident reporting procedure)

Incident: Any untoward or unexpected event which interferes with the orderly progress of day to day activity and which results in, or could have resulted in:

i. Damage or loss to property.

ii. Harm to an individual or individuals (non-clinical)

iii. Harm to Equipment, Vehicles, Materials, Buildings or Property.

Clinical Incident: Any untoward or unexpected event which interferes with the treatment of a patient and which results in, or could have resulted in, inappropriate or inadequate clinical care, an injury or serious injury.

Minor Incident: Incidents & near misses that do not affect the day to day running of the clinic nor impact the health and safety of staff or patients. The Minor incident log is reviewed by the Service Manager monthly to identify repeat occurrences over time.

Moderate Incident Incidents that could have an impact on the running of the clinic or pose some threat to the health and safety of patients or staff (But no actual harm has occurred) Moderate incidents are individually assessed and followed up by the Service Manager

Serious Incident: A Serious Incident is defined when a patient, member of staff, or member of the public suffers serious harm or unexpected death on Company premises, or premises where the Company provides services. Where staff actions are likely to cause significant public concern; Any event that might seriously impact upon the delivery of service plans and/or may attract media attention and/or result in a settlement following litigation and/or may reflect a serious breach of standards of service.

Harm: Injury (physical or psychological), disease, disability or death. In the case of incidents arising during patient care. Harm can be considered 'unexpected' if it is not related to the natural cause of the patient's illness or underlying condition. Adverse outcomes related to natural course of illness or proper treatment in accordance with accepted clinical standards are therefore **NOT** classed as clinical incidents.

Hazard: A hazard can be defined as: "anything that can cause harm". Hazards are situations with the potential to cause harm or damage and could include faulty equipment, worn or loose floor coverings, irritant chemicals etc. Incident reporting forms must be completed for all hazards. Individual responsibilities are not however discharged by the mere completion of an incident reporting form and all reasonable steps should be taken at the time to minimise the risk of injury arising from any identified hazard.

Near Miss: A clinical or non-clinical incident where no immediate harm, loss or damage was suffered, but if not reported & investigated could reoccur.

Never Event: Never events are a sub-set of Serious Incidents and are defined as 'serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers. (See Appendix 4 for partial list).

ACTIONS TO BE TAKEN IMMEDIATELY FOLLOWING AN INCIDENT

Some incidents will require prompt and specific action to deal with the problem. This may include the following:

- Summoning assistance & Emergency medical care
- Ensuring all at risk; patients, staff, visitors and others, are moved to a safe environment
- Treating/caring for others affected
- If equipment / machinery is involved, removing it from service (marking it clearly 'out of order').
- Notifying senior members of staff on duty
- Formally reporting the incident via the department's Incident Log.
- If applicable - Recording the action taken in the patient's medical records. Records might not be at hand, but they should be found and either tracked or made secure.
- If applicable - Request that all those who observed what happened prepare a witness statement as soon after the event as possible.

INCIDENT REPORTING

See: APPENDIX 1 Incident Process flow chart

All incidents (including near misses) must be recorded in writing (in the Excel INCIDENT Log).

ALL incidents need to be investigated so that the Company can learn lessons and, if necessary, modify practice to prevent re-occurrence. There are sections within the Incident Report to record actions taken and lessons learned, and these must be completed before the incident is closed.

Immediately a staff member becomes aware of an incident, they must ensure all steps are taken to make safe the person(s) and the environment involved, liaising with other individuals as necessary to achieve this.

Minor Incidents are expected to be resolved at the scene / time of occurrence, by the member of staff concerned, and are recorded so that subsequent review can identify any repetition or ineffective resolution.

Moderate and Serious Incidents are expected to be resolved as much as possible at the scene / time of occurrence and are recorded so that the Service Manager and other relevant personnel can investigate and fully resolve matters, in line with this policy and company procedures.

If the person involved in an incident is unable to complete the incident report form for any reason, then a witness or colleague should do so on their behalf.

- All information given, including written statements must accurately state the facts, without expressing personal opinion or allocating blame.
- Incident report forms should be completed as fully as possible for all types of incidents.
- Once the form has been completed it should be submitted / given to the appropriate manager.

For all incidents other than Minor Incidents, the Service Lead (or the Health & Safety Lead) must be informed ASAP.

The Manager will then ensure the Incident documentation has been correctly & fully completed and will undertake an immediate assessment of the seriousness of the incident and create an action plan of those that require further attention.

All staff have a responsibility, set out in this policy, to escalate incidents as potential Serious Incidents (SI) if the incident meets the national SI criteria. If staff are unsure, they should discuss with their line manager or the Health & Safety Lead.

REPORTING TO EXTERNAL AGENCIES

Following a Moderate or Serious Incident report, the Manager will liaise with the Health & Safety Lead and relevant personnel to provide root cause analysis and generate a report for the Director(s).

The Health & Safety Lead will report all Serious Incidents to Service Commissioners or Client using the STEIS system (or alternative locally preferred mechanism).

MANAGING NON-SERIOUS INCIDENTS

Near-Misses

A Near-Miss is an incident that, on this occasion, had no effect on service provided, but the staff member has seen that in different circumstances it could have become a significant event. It might be related to service provision, processes in place, staff, patients or buildings or any other matter.

Near misses are opportunities for us to improve the service we provide.

A Near-Miss Form should be completed so that the matter can be reviewed by the Service Manager. See Near-Miss Reporting Form template - Appendix 3

Negligible & Minor Incidents

All negligible or minor incidents should provide a summary of the immediate action taken following the incident by the initial reporter in the Incident log.

Minor incidents will be reviewed by the Service Manager at the monthly Incident log review, so the details provided should be as complete as possible.

Incident trends (which include negligible & minor incidents), the lessons learnt, and actions taken, will be reviewed through the Governance Leads and Director(s).

Moderate Incidents

All moderate incidents should provide a summary of the immediate action taken following the incident by the initial reporter in the incident log. The Further Action required tick box should be activated for individual review by the Service Manager.

The Manager will decide whether a full Investigation and Incident report is required and complete such if applicable.

Incident trends (which include moderate incidents), the lessons learnt and actions taken will be reviewed through the Governance Leads and Director(s).

In line with the Company's "Being Open Policy", where applicable moderate and more severe incidents will be discussed with the patient or other 'injured party' to identify the nature of the incident and the follow-up actions that have been taken to redress the situation and minimise the chance of repetition.

MANAGING SERIONS INCIDENTS

Defining a Serious Incidents

When reporting an incident, staff should class the event as a Serious incident if their professional opinion feels it appropriate, even if it does not meet the criteria for a formal, notifiable, Serious Incident as shown below.

A formal Serious Incident requiring investigation is defined as an incident that occurred in relation to care services resulting in one of the following:

- Unexpected or avoidable death of one or more patients, staff, visitors or members of the public;
- Serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm);
- A scenario that prevents or threatens to prevent the Company's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure;
- Allegations of abuse/ neglect (safeguarding)
- Adverse media coverage or public concern about the organisation or the wider services;
- One of the core set of 'Never Events' as updated on an annual basis see Appendix 4

The above is applicable where an incident is classified as an event of circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public.

Reporting requirements for Serious Incidents'

Serious Incidents will be reported as with all other incidents on an Incident Report. Additional people will be contacted as soon as possible as outlined in the process chart at APPENDIX 2

Reporting and Investigation of Serious Incidents

Serious Incidents must be declared internally as soon as possible, and immediate action must be taken to establish the facts, ensure the safety of the patient(s), other services users and staff, and to secure all relevant evidence to support further investigation. Serious Incidents should be disclosed as soon as possible to the patient, their family (including victims' families where applicable) or carers.

Previous, the National Framework for Reporting and Learning from Serious Incident Requiring Investigation (NPSA 2010) and the supplementary guidance issued by NHS Commissioning Board Serious Incident Framework (2013) requires that all Serious Incidents (SIs) are reported on the STEIS system within 48 hours of knowledge of the incident.

This guidance has now been replaced by the **Serious Incident Framework (March 2015**), but the same 48 notification period remains. The future of patient safety is currently under review by NHS Improvements.

Other regulatory, statutory and advisory bodies, such CQC, will be informed as appropriate without delay. Discussions will be held with other partners (including the police or local authority for example) if other externally led investigations are being undertaken. This is to ensure investigations are managed appropriately, that the scope and purpose is clearly understood (and those affected informed) and that duplication of effort is minimised wherever possible.

If there is uncertainty about the status of an incident, Southern Ultrasound will err on the side of caution and assume the worst. If in doubt, advice will be sought from the Client management or Commissioner.

All Serious Incidents will be fully investigated using Root Cause Analysis techniques by the Health & Safety Lead, or another Governance Lead if the former is unavailable or involved in the incident. In addition, adverse trends that are identified as part of the trends analysis of incidents may also trigger a more in-depth RCA investigation. All staff are required to support and assist the investigation as necessary and instructed.

The purpose of the investigation shall be to:

a. Establish the accurate facts of the incident from whatever sources are necessary;

b. Ensure that all immediate necessary actions have been implemented to safeguard patients, the Client and the Provider.

c. Ensure that the confidentiality of the patient is maintained in the context of the incident

d. Establish whether there is a risk of repetition of the incident and if so the mechanism to reduce such risk.

e. Establish whether there is a need to modify the policies or procedures or the Client or the Provider.

f. Establish whether there is a training need.

The lead investigator shall be responsible for:

- Determining the conduct of the investigation and agreeing terms of reference for the investigation with the Director(s).
- Applying Root Cause Analysis methodology to identify all the care & management issues
- Requesting written accounts from relevant persons for the purpose of the investigation,
- Interviewing relevant persons, the staff member will be given a copy of the interview notes for them to read, sign, date and time;
- Setting up a round table RCA meeting to review the incident;
- Providing a chronology of events;
- Providing update reports on progress with the investigation to the relevant Service Team and Director(s); and
- Providing a draft report within 4 weeks of notification of the incident occurring;
- Providing a final report within 6 weeks, in the accepted Company format, that identifies the specific and general contributory factors and indicates any issues to be addressed (or recommendations) for action by the appropriate Service Team and the Director(s) to prevent recurrence;

- Ensuring feedback is given to the staff and the patient/family involved in the incident highlighting the care and service delivery problems identified.

Where an incident involves another organisation lead investigator will be responsible for liaising with the other organisation to ensure that they are aware of any matters which they may need to investigate.

In cases of more complex incidents, a multidisciplinary team may be required to fully investigate an incident, or, to ensure objectivity, there may be a need for an independent investigation. In these cases, the Health & Safety lead will seek external guidance from the Service Commissioner or other advisors.

It is the responsibility of the service lead / senior manager where the incident occurred to ensure that as recognised by the investigation, all learning points and safety improvements are appropriately identified and action plans drawn up, implemented, monitored and reviewed.

The National Framework requires that such incidents are subject to robust investigation to establish the root cause/s of the incident and to make recommendations as to what actions are required to prevent or minimise the likelihood of the incident happening again.

Depending on the type of incident, Southern Ultrasound' Board of Directors will approve the final investigation report detailing the investigation, findings, recommendations and outlining an action plan. The Board will monitor to ensure the actions required are implemented.

STAFF SUPPORT FOR THOSE INVOLVED IN AN INCIDENT

Conduct of investigation

Southern Ultrasound shall endeavour to ensure that all investigations are conducted in a manner that is demonstrably supportive to those involved. The process must be seen as being about listening, learning and improving. This will include providing those who are being investigated with a full account of the reasons for the investigation, giving them a proper opportunity to talk to the Lead Investigator and ensuring that they are kept informed of progress. Also any findings of the investigation and response to third parties must be shared with those whose actions are being investigated.

It will be the role of the Company Directors and Senior Managers, to be alert to those factors, which may necessitate and provide the necessary resources for this to take place. The welfare of any staff involved in an incident will be considered particularly in relation to psychological trauma or stress.

Such support may take different forms depending on the type of incident and the level of involvement of the staff member or the physical or mental injury suffered by the individual. Support may include:

Personal Debrief

The personal debrief is where the manager and the staff member involved sit in private and discuss the incident in an uncritical atmosphere.

Leave Arrangements

Leave may be taken as sick leave, annual leave or compassionate leave dependent on the circumstances of the incident. When leave is taken following an incident due to personal injury or to a member of staff not being fit to work for any other reason, including stress related reasons; a return to work de-brief will occur before duties are assumed

Occupational Health Support

The Service Lead is authorised to refer the individual for counselling at the Companies expense if it is appropriate. The Board of Directors shall be informed of this action and will have the responsibility of setting limits on this support and its financial implications.

Communication with staff involved

Staff will be kept fully informed of the progress of an investigation with which they have had clear associations. This will be the responsibility of the Health & Safety Lead undertaking the review or chair of any investigation team.

In particular staff, must be kept aware of progress and when the report has been completed, the findings, recommendations and action to be taken will be relayed to them, giving them the opportunity to ask questions.

SUPPORT FOR PATIENTS / CARERS / RELATIVES

Every effort will be made to inform the individual involved as soon as possible before any media contact is made and in line with the Being Open Policy.

The individual will receive treatment, care and support, and be given full information on the incident, including the outcome of the investigation. If the individual is incapacitated then next of kin and or significant other, will be informed in lieu of the patient. Where the incident has led to death or serious injury, the individual's next of kin will be informed before any media contact is made.

COMMUNICATION WITH MANY AFFECTED INDIVIDUALS

It is acknowledged that on occasion, particularly where many patients have been involved or the incident has come to light some months later, it may not be possible to inform the individuals affected prior to the media becoming aware, although it will be the responsibility of the Clinical Governance Lead to ensure every effort to do has been demonstrated.

There may be circumstances where there are multiple enquiries needing to be responded to, or a complex, high profile incident needing well coordinated action planning and implementation. In these events hotline arrangements will be implemented, most likely, in conjunction with the Service Commissioner.

LIASON WITH OTHER INTERESTED PARTIES

Official Bodies

It is the responsibility of the Health and Safety Lead (or, in their absence another Governance Lead) to determine whether external bodies are to be involved in the investigation, based on the detail of the incident itself. It will be the responsibility of the Lead Director to inform and involve any organisation as appropriate; this may include one or more of the following:

- Professional body, e.g. NMC, GMC, HCPC
- Health and Safety Executive
- GPs (particularly if the incident involves many patients), NHS England,
- Client NHS Trust, other NHS Trusts where applicable.
- NHS Litigation Authority/ Trust legal Advisors
- Police/ Coroner/ Social Services
- Medicines and Healthcare products Regulatory Agency
- Child Protection Agency

N.B: This list is not exhaustive

Communications with Media

In circumstances where there is actual or anticipated media interest in an incident, then the Information Governance Lead will be responsible for dealing with the Company's response to the media, in conjunction with the Board of Directors. It will be the responsibility of the Information Governance Lead to make every effort to ensure staff are briefed on how to deal with the media should they be approached.

RISK REDUCTION MEASURES & ACTIONS PLANS

Following completion of an investigation where a patient has suffered serious injury or death or the incident is a never event the Lead Investigator will prepare and circulate a template action plan populated with the issues to be addressed, for comment by the relevant Service Lead.

The Service Lead will be responsible for identifying actions in response to the identified issues to be addressed. The plans must indicate the actions to be taken, the timescale for the actions to be completed, the relevant leads for the actions and any update on progress. This action plan will be developed and presented at the Board of Directors by the Health and Safety Lead to ensure a timely response to the issues identified, in line with the National Framework.

The Health & Safety Lead will take ownership of the action plan(s) and ensure the implementation is closely monitored. Effective and timely implementation of actions is required to ensure that lessons are learned following a serious incident occurring.

SAFEKEEPING OF INVESTIGATION RECORDS

The Board of Directors will be responsible for ensuring the safekeeping of collated information and reports, including original notes or photocopies if notes are still needed for patient care, and imaging if necessary.

DISCIPLINARY ACTIONS

Southern Ultrasound recognises that the most incidents occur as a result of an accumulation of a number of factors and events all conspiring together. Staff are encouraged to report incidents without fear of disciplinary action in a culture of learning and fair blame. Fear of disciplinary action may defer staff from reporting a serious incident.

The view of the Company is that disciplinary action should not form part of a response to an incident except in cases where one or more of the following apply:

- Where in the view of the Company, and / or any professional registration body, the actions causing the incident / arising from the incident were far removed from acceptable practice
- Where there was intent to harm and / or criminal offence has taken place
- Where there is failure to report an incident in which the member of staff was either involved or about which they were aware

To ensure a robust and consistent approach to incident investigation, the Company will use the NPSA's Incident Decision Tree (IDT) where possible:

TRAINING

Risk management, Patient Safety, and Health and Safety training are identified in the Company's Training Needs Analysis. Managers and Staff are obligated to ensure they undertake the required training as relevant to their job role and personal learning plan. This applies to both those employed under contract or on the premises in any other circumstance e.g. as a subcontractor.

Training needs and feedback following an incident will be established by the H&S Manager and provided at Team Briefs or dedicated learning sessions, as deemed most suitable.

LEGISLATION & GUIDANCE

- NHS Improvement - Serious Incident Framework 2013
- NHS Improvement – Revised Serious Incident Framework March 2015
- Health and Safety Executive: RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 http://www.hse.gov.uk/riddor/
- NHS Improvement - Reporting a Serious Incident to the Strategic Executive Information System (StEIS)
- Environmental Permitting (England & Wales) Regulations (2010)
- World Health Organisation: The Conceptual Framework for the international Classification for Patient Safety. (2009)
- National Patient Safety Agency: Being Open: Communicating patient safety incidents with patients and their carers (2005)
- Root Cause Analysis Toolkit National Patient Safety Agency (2004)
- Seven Steps to Patient Safety National Patient Safety Agency (2004)
- Health & Social care act 2008 (regulated activities) regulation 2009
- Corporate Manslaughter Act 2007
- Criminal Justice Act 2003
- Health and Safety at Work Act 1974

DISTRIBUTION & AWARENESS PLAN

All staff are made aware of the policy as part of their induction training. If there are any significant changes to the policies that affect the way in which staff initiate or respond, these are communicated to them via email, team briefs and staff meetings.

A copy of the policy is available to all staff via the Policy sub-folder of the Company's on-line Governance Framework folder, and can be accessed 24/7 from any location with Web Access. A hard copy version is retained at all sites of operation.

EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment has been performed on this policy and procedure. The EIA demonstrates the policy is robust; there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Title: Incident Reporting Policy – Including Serious Incidents.		
Analysis	**Yes / No**	**Comments**
1 Does the policy/guidance affect one group less or more favourably than another on the basis of:		
Race	No	
Ethnic Origins	No	
Nationality	No	
Gender	No	
Culture	No	
Religion or Belief	No	
Sexual Orientation	No	
Age	No	
Disability – learning or physical, sensory impairment or mental health	No	
2 If there any evidence that some groups are affected differently?	No	
3 If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4 Is the impact of the policy/guidance likely to be negative?	No	
If so can the impact be avoided?	N/A	
What alternatives are there to achieving the policy/guidance without the impact?	N/A	
Can we reduce the impact by taking different action	N/A	
Will the policy affect a person's right to life?	No	
Will someone be deprived of their liberty or have their security threatened?	No	
Could this result in a person being treated in a degrading or inhuman manner?	No	
Is there a possibility that a person will be prevented from exercising their beliefs?	No	
Will anyone's private and family life be interfered with?	No	

POLICY MONOTORING & REVIEW

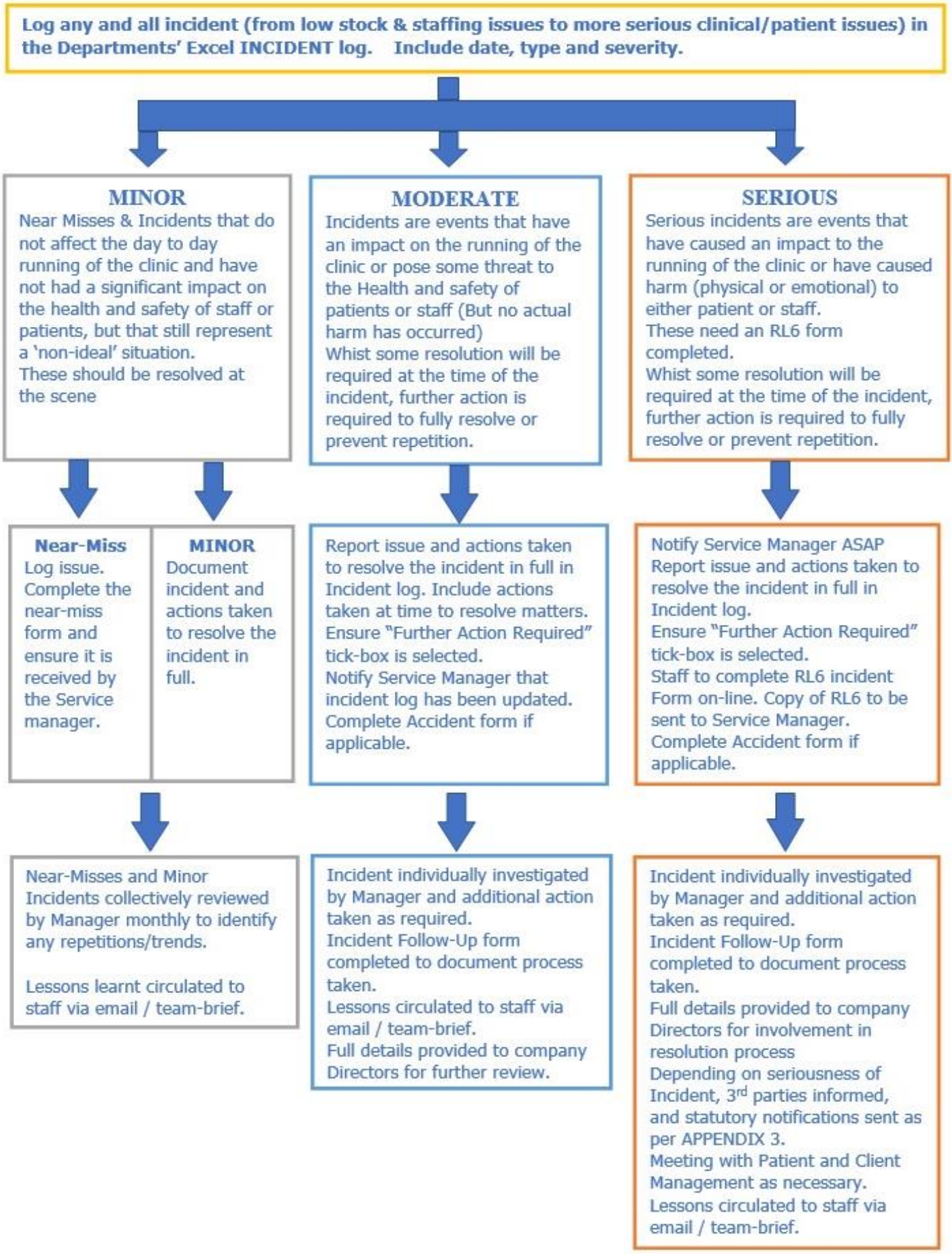
The Incident and Serious Incident Reporting and Management Policy will be reviewed annually and monitored for effectiveness by the following processes:

- Incident reviews at Board Meetings
- Review of NRLS Feedback Reports
- Annual incident trend analysis reports to the Board of Directors

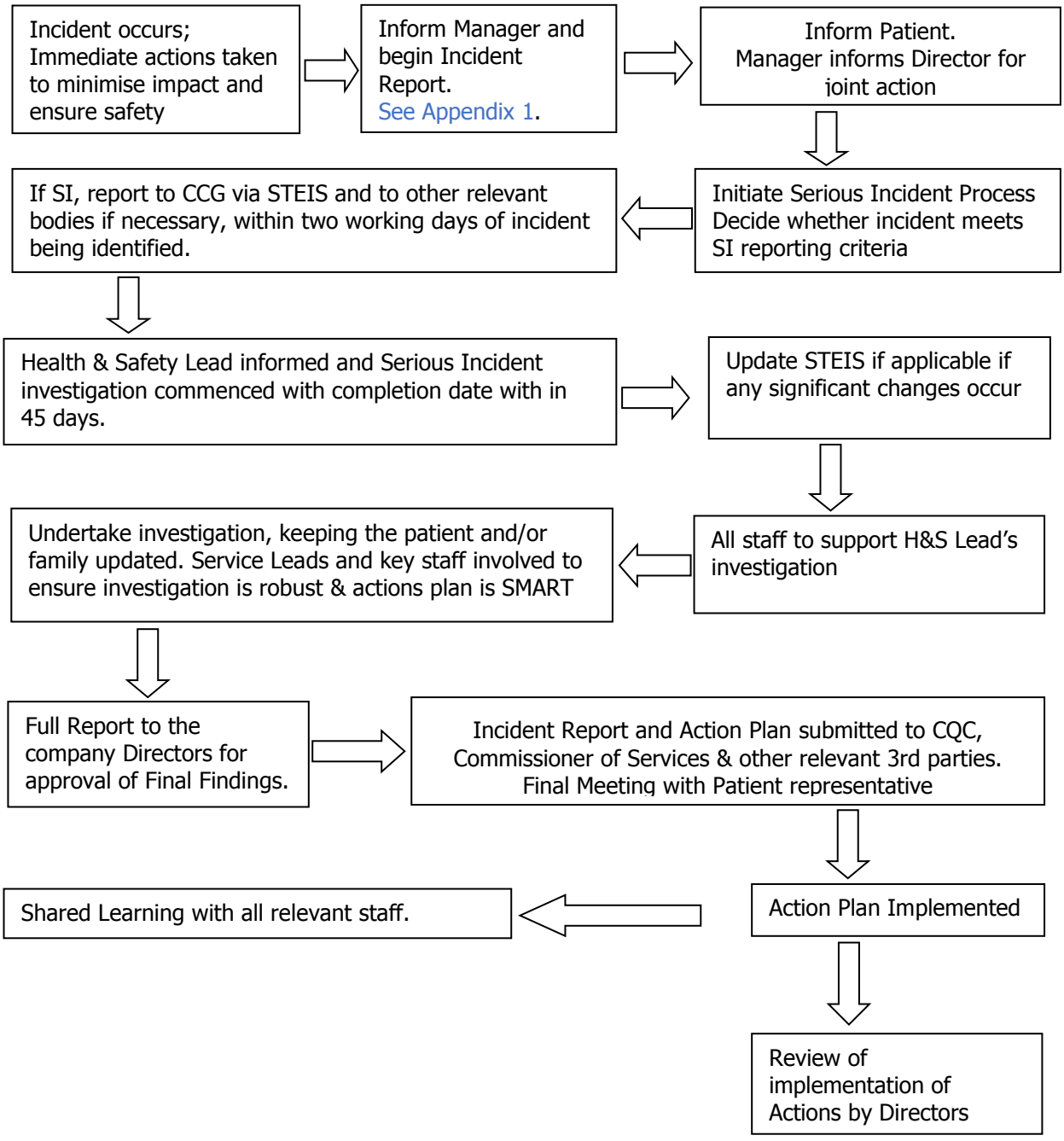
Policy Created: 21/08/18 Policy Reviewed & Amended: 13/05/19 V2

Kevin Rendell Director

APPENDIX 1. INCIDENT PROCESS – FLOW CHART [FHNHSFT)



APPENDIX 2. SERIOUS INCIDENT STEPS – REPORTING FLOW CHART



APPENDIX 3. NEAR-MISS REPORTING FORM

Copies of this template are to be found in every scan room. Near misses should be recorded in the Department's Incident log and this form completed and sent to the Service Manager.

A near-miss is a potential hazard or incident that has not resulted in any personal injury or property/equipment damage. Examples would include; unsafe conditions, improper use of equipment, faulty equipment, not following correct procedures …

It is everyone's responsibility to report and correct any of these potential hazards immediately, and to advise of areas where safety can be improved.

Please use this form to report near-misses and safety concerns / recommendations; so that the Company management is informed of the issue, can assess the actions taken to minimise a repeat or worse occurrence, and can implement additional longer-term strategies to ensure lessons-learnt are applied across the company and its stake-holders.

Your Name. (Optional) : ..

Date Report Created: ..

Date of incident: ..

Time of incident (approx. if not relevant to issue): ..

Mark ALL appropriate conditions:

- ☐ Near-Miss
- ☐ Safety Concerns
- ☐ Safety Suggestion
- ☐ Other (Describe) ……..

Type of concern:

- ☐ Unsafe Act
- ☐ Unsafe Conditions of location (a room, location or area)
- ☐ Unsafe Conditions of Equipment
- ☐ Unsafe Use of Equipment (risk more related to 'persons' rather than 'items')
- ☐ Other (Describe) ……..

To the best of your knowledge; is this incident?

- ☐ A One-Off incident, and unlikely to repeat
- ☐ A One-Off incident, but IS likely to repeat if further action is not taken
- ☐ An incident that has or is likely to have happened previously

Have you had to removed equipment from use?

- ☐ Yes (If so, it must be clearly labelled and removed from the clinical area)
- ☐ No

Describe the Potential incident / hazard / concern and possible outcome (what could have happened if the near-miss was not averted) in as much detail as possible

Immediate Action Taken to Prevent Recurrence

Describe Any Additional Safety Suggestions

Once completed, send this form to the Service Manager or Company Director without delay.

Please leave next page blank

For OFFICE USE:

Report assessed by: …..

Date: ….

Additional actions taken:

Lessons Learnt in brief:

Manner lessons-learnt disseminated to staff:

APPENDIX 4. NEVER EVENTS

Never events are a sub-set of Serious Incidents and are defined as 'serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.

The list below is far from exhaustive but demonstrates some of the potential occurrences for the work of Southern Ultrasound:

- Misidentification of patients
- Suicide using non collapsible rails
- Escape of a transferred prisoner
- Falls from unrestricted windows
- Entrapment in bedrails
- Misplaced naso- or oro-gastric tubes
- Failure to monitor and respond to oxygen saturation
- Misidentification of patients
- Severe scalding of patients

A complete list of NHS' categorised Never Events is available at :

https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf

APPENDIX 5. REPORTING A DEFECT OR INCIDENT

Incidents involving equipment will be reported in the same way as any other incident.

The equipment will be withdrawn from service immediately, quarantined, labelled 'Defective Do Not Use' and handed over to the Service Lead for further investigation.

Whenever practicable the device controls and settings should remain in the same position as when the incident occurred and all relevant information must be documented.

Until a formal investigation has been completed, they will not be:

- Discarded
- Repaired
- Returned to the manufacturer

They will be:

- Clearly identified and labelled
- Stored securely

MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely. One way they aim to achieve this is by investigating reports of adverse incidents involving medical devices and, where appropriate, instigating corrective actions to reduce the risk of recurrence.

Dealing with the manufacturer

The manufacturer or supplier should be informed promptly of incidents and, if accompanied by an appropriate person, may be allowed to inspect the items this will be coordinated by the Lead investigator. To facilitate an investigation, it may be possible to provide the manufacturer with a sample of unused stock from a large batch. However, until advised to the contrary by the MHRA, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident as this might prejudice our investigations, or those of other official bodies.