Objective

This SOP ensures patient and donor safety by requiring that incidents that could impact on the safety and quality of NHSBT's products and services are reported to Quality Assurance (QA).

Changes in this version

Update of the procedure to the new SOP format, therefore no highlighting. Included change request CR45087 – include reference to Courier events and CR45804 – expand Stop, Isolate, Escalate, instructions to use the web reporting tool on Link.

Roles

- All staff within NHSBT

Restrictions

- Events and Incidents in ODT are managed through SOP3888 - Reporting an Organ Donation or Transplantation Incident to NHSBT.
- Courier events are logged by Transport using SOP5649 - Management of Courier Complaints in Qpulse Occurrence module.

Items Required

- None

Instructions

All staff

1. Identify the incident.

1.1 Identify that something unwanted, unexplained, or unexpected has happened that has potential to impact:

- Patient or donor safety
- Product quality
- Supply chain
- Business Continuity
- Information Governance
- Procurement

2. Take immediate action.

2.1 **STOP** the activity being performed.

2.2 **ISOLATE**. Ensure no further incidents can occur. Perform action(s) to contain the incident e.g.:

- Check to see if there are instructions for managing the incident (e.g. DAT/MPD/SOP) and follow as instructed.
- Quarantine consumables/equipment.
- Place holds on products.

2.3 Review with person in charge or QA if person in charge is not available (QA Direct 0161 423 (5) 4300 between 08:00-17:00, your local QA department or national QA on call 07000 781778 out of hours).

2.4 Manage the incident according to the procedure for the process that has been impacted, or as instructed by the person in charge and/or QA.

3. Does this incident need to be escalated?

3.1 You must **ESCALATE** any incident where it has the potential to impact patient/donor safety, product quality, supply chain, Business Continuity, Information Governance or Procurement, unless the authorised instructions within a procedure to manage the incident have been followed and removed any requirement for further actions, or QA have confirmed that it does not need to be raised. This should be within one working day of the incident being identified.

→ If NO ⊖ End of Procedure ⊖

→ If Yes go to Step 4

4. Gather information.

4.1 Gather all relevant information about the incident:

- **What happened**: document what the main problem was, with an overview statement. Be clear and concise.
- **What/who was involved**: Include all relevant details e.g. serial numbers of equipment, donor number, donation number (including check digit), donation type e.g. CVP.
- **Risk and impact of the event**: what was the risk or impact to the patient, donor, product quality or safety, supply chain or service. Consider Duty of Candour (MPD1224).
- **Impact of the event**: was there any impact on Business Continuity, Information Governance or Procurement.
- **Immediate actions taken**: what was done to manage the risk, contain and resolve the problem. Consider mitigation of risk as well as immediate actions. Document what products are on hold and hold code, what equipment/consumables have been quarantined.
- **Indicate the suspected cause of the incident**: from initial investigation what caused the incident.

⚠ Caution

If you have access to a NHSBT computer or iPad, incidents must be submitted electronically using the Incident Report form in the Occurrence Module in Q-Pulse or the reporting tool on Link.
If completing FRM404, FRM1524, FRM4544 these are to be completed electronically, then emailed to QA Direct Enquiries.
If completing FRM1 by hand, these are to be scanned and emailed to QA Direct Enquiries.
If completing FRM6079 attach to Incident Report when raised.

5. Document and submit the incident.

5.1 Document and submit the incident within one working day by:

- Complete Incident Report form in Q-Pulse Occurrence module. Responsible dropdown is QA.

  OR
- Complete Incident Report form using the reporting tool on Link – I need to – Report a Quality Incident

  OR
- Email electronically completed FRM404, FRM1524, FRM4544 to QA Direct Enquiries with FRM404, FRM1524, FRM4544 in the subject title

  OR
- Scan and email handwritten FRM1 – Incident Report to QA Direct Enquiries, with FRM1 in the subject title.

5.2 If appropriate, attach additional information to the email or with the submitted incident using naming convention in DAT2479:

- E.g. photographs, screen shots, photocopies.
- FRM6079 for out of specification Environmental Monitoring results.

⊖ End of Procedure

Definitions

- N/A

Related Documents/References

- DAT2479 – Referencing and Embedding Files in Q-Pulse
- FRM1 – Incident Report
- FRM404 – Therapeutic Apheresis Services – Adverse Event Report
- FRM1524 – CST Report of SAED to QA
- FRM4544 – Record of Medical Consultation
- FRM6079 – Out of Specification EM Reporting Form
- MPD1224 – Being Open and the Duty of Candour

Appendices

N/A