Document Details

Document Number: SOP:07:QA:070:08:NIBT  No. of Appendices: 1
Supersedes Number: SOP:07:QA:070:07:NIBT

Document Title: PROCEDURE FOR REPORTING AND MANAGEMENT OF QUALITY INCIDENTS

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Document Authorisation/ Issue & Implementation

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RA&C Manager

ISSUE DATE: 03 March 2014  EFFECTIVE DATE: 12 April 2014

CROSS REFERENCES
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Key Change from Previous Revision:

Major re-write of SOP in response to MHRA inspection
Expansion of 1.1 re all staff and addition of responsibilities of root cause analysis experts and investigators
Time lines for incident closure reduced from 60 days to 30 calendar days.
Clarification that assignment of incident scoring is based on potential risk or actual harm to patient/donor.
Definitions for different categories of incident added.
Risk Matrices updated to include detectability and requirement to score a severity 5 risk where patient suffers serious harm or death as Red regardless of potential for recurrence.
Addition of requirement for Departmental Head to formally review the remedial action taken to ensure appropriate.
Inclusion of reference to SOP:QA:110 Techniques to be Employed During Quality Investigation.
Reference to UKAS

1 RESPONSIBILITY

1.1 It is the responsibility of all members off staff to report incidents and participate in the investigation of to determine the root cause; therefore this procedure will require to be followed by most staff members at one time or another.

1.2 The initial report should be made by the person who makes the observation of the non-conformances/problems/errors/deviations or potential non-conformances/problems/errors/deviations, (i.e. responsibility for reporting should not be delegated). Need for recall of components must be considered at time of initial report.

Note: Non-conformances/problems/errors/deviations are generalised within the rest of the document as Incidents

1.3 Quality function will establish and maintain a system for recording all incidents raised within Northern Ireland Blood Transfusion Service (NIBTS).

1.4 Follow-up will normally be managed by the relevant department manager or deputy. However, incident management may involve a wide range of inputs, including relevant Senior Managers and relevant Incident Review forums as specified this SOP.

1.5 Incident investigators are responsible for gathering data and evidence to determine the root cause of the incident and for documenting in a clear and accurate manner

1.6 Root cause analysis experts are responsible for providing advice and assistance to incident investigator in determining the optimum tools for root cause analysis and their application.

1.7 It is the department manager’s responsibility to consider any risks arising from incidents and where appropriate ensure additions to departmental risk registers as detailed in SOP:RM:001 ‘Risk Register Process’.
1.8 The incident stages will be progressed using Q Pulse quality incident template. The population of the template is the responsibility of the Regulatory Affairs & Compliance Lead (RA&C Lead) or Regulatory Affairs & Compliance Manager (RA&CM).

1.9 Incident stages and actions will be tracked by the Regulatory Affairs & Compliance department to ensure timely completion. If this is found not to be the case the department will be informed by the RA&C Lead or RA&CM.

1.10 The decision on whether there is satisfactory documented evidence for incident closure will be taken by the RA&C Manager or RA&C Lead. The incident report file will be held on Q Pulse and any supporting hard copy documentation such as the investigation held by the RA&C Department until archived in an approved manner.

2 INTRODUCTION

2.1 GENERAL

2.1.1 This SOP describes the procedure to be used for incident reporting and management within NIBTS. It is important to note that the purpose of incident reporting is to help NIBTS improve quality and reduce risks to patients, donors and staff. The purpose is not to lead to the disciplining of staff who make genuine errors. However, deliberate failure to report incidents and comply with this procedure could lead to disciplinary action being taken.

This SOP provides a standardised procedure for reporting quality related incidents which is intended to meet the following requirements:

- The requirements of the Blood Directive and of the MHRA Guidance on SABRE reporting
- The requirements of the European Tissue and Cells Directive (EUTCD) 2004/23/EC, the Human Tissue Act (2007) and of the current HTA Directives and Guidance
- The requirements of the CPA/UKAS
- The requirements of the DHSSPS/HSCB and relevant Controls Assurance Standards including Risk Management
- NIBTS strategy regarding risk management (STG:RMS:001 Risk Management Strategy)

2.1.2 A Quality Incident is an event which causes, or has the potential to cause, unexpected or unwanted effects that will involve the safety of patients, donors, staff, users and other people. Such events indicate a failure of the GXP process.

Incidents may be identified at any stage of the donor recruitment, blood (including cord blood) collection, transport, processing, storage, distribution and transfusion process.

Incidents may also be identified during the provision of NIBTS Patient Testing services.
2.1.3 All incidents must be fully reported and, where appropriate, further investigation undertaken. This procedure sets out the requirements and responsibilities of staff, the means of reporting an incident as it is identified, investigation of underlying cause(s), and appropriate and timely corrective actions according to the nature of the incident. It is recognised that immediate remedial action may be required before the full investigation has been completed.

Incidents will be assessed for root cause. Some complex and serious incidents will require formal root cause analysis.

**Note:** Incidents which are classified as “serious” will be reported to relevant external authorities e.g. Serious adverse events (BSQR definition) will be reported to SABRE using the procedures defined in SOP:QA:079 – ‘Reporting Serious Adverse Events or Reactions to SABRE’.

Preventive action, such as implementing modifying or enforcing procedures or controls, will be taken to avoid repetition of the incident, or prevent a potential incident from occurring. Any corrective or preventive action taken to address the causes of an actual or potential incident must be appropriate to the magnitude of incident, and formal quality review will take place.

2.1.4 This SOP does not cover a number of areas where there are alternative reporting systems in place as follows:

- Faults reported for Individual blood packs or apheresis harnesses (see SOPs QA:016 ‘Procedure For Reporting Blood Pack Faults’ and SOP:PH:047 ‘Procedure For Handling Apheresis Machine And Harness Defects’ Incorporating Apheresis Related Incident Reporting’).
- Accidents involving staff, donors or patients (Health and Safety – see SOP HS:012 ‘Procedure For Reporting And Managing Health and Safety Incidents’)
- Donor complaints (See SOP BD:017 ‘Procedure For Processing Complaints And Other Donor Contacts’).

2.1.5 Some incidents are reported to facilitate monitoring of their level of occurrence, and will not require the scoring, investigation or review stage to be carried out. An increase in the occurrence of such incidents may however necessitate the raising of a further incident, which will require these steps to be undertaken. The following incidents are examples of those which may fall into this category.

- Individual incident reports of cracked/leaking frozen components.
- Individual incident reports of red cell components which have been determined by the hospital blood banks to have a positive Direct Coombs Test.
- Incident reports raised where a component has been found in an ‘empty’ blood box returned from a hospital.
- Incident reports raised as a result of an Antenatal Test been undertaken when the sample has not meet the minimum criteria for testing but has been deemed urgent by the sender and the NIBTS Medical Director/Deputy (as per POL:MP:011 – Policy For Receipt of
Samples Which Do Not Conform With NIBTS Sample Labelling or Request Form Requirements).


2.1.7 Where an incident is raised to monitor level of occurrence, the Regulatory Affairs and Compliance Manager/Deputy will close the incident and acknowledge/inform the sending hospital/department of its receipt as appropriate.

2.2 CLINICAL RELEVANCE/ PURPOSE OF EXAMINATION

Not Applicable.

2.3 PRINCIPLE OF EXAMINATION

Not Applicable.

3 HAZARD AND SAFETY PRECAUTIONS

3.1 There are no Health and Safety issues relating to the application of this SOP.

4 MATERIALS

4.1 EQUIPMENT AND SPECIAL SUPPLIES

4.1.1 There are no specific materials required for this SOP.

4.2 SPECIMEN REQUIREMENTS AND MEANS OF IDENTIFICATION

Not Applicable.

4.3 REAGENTS, STANDARDS OR CALIBRANTS AND INTERNAL CONTROL MATERIALS

Not Applicable.

5 CALIBRATION

Not Applicable.
6 PROCEDURE

Incident Management Overview

The incident management process overview to be followed summarised below:

- **Incident or Potential Incident Identified**
- **Quarantine Product (When Applicable)**
- **Investigation Performed (Root Cause Analysis)** (Form DD:951 – Section 1)
- **Corrective/Preventive Action Identified/Agreed and Progressed** (Form DD:951 – Section 2A initially then quality incident template CA/PA stages)
- **Corrective/Preventive Action Implemented and Effective** (Completion of Department Sign Off stage in template)
- **QA Final Review and Closure**
- **Document actions or rationale for no requirement for Corrective/Preventive Action** (Form DD:951 – Section 2B)
- **Risk Assessment (If Required)**
- **Corrective/Preventive Action Required?** (Form DD:951 – Section 2)
- **End of Process**

**Trend Incidents and review.** Present data to Senior Management

**Feedback to Originator on Completion of Incident to the Final Outcome**

**Yes**

- Corrective/Preventive Action Implemented and Effective
  - QA Final Review and Closure
  - Feedback to Originator on Completion of Incident to the Final Outcome

**No**

- Corrective/Preventive Action Required? (Form DD:951 – Section 2)
  - Document actions or rationale for no requirement for Corrective/Preventive Action (Form DD:951 – Section 2B)

**Rejected not an Incident**

- Quality function Review and population of quality incident template
  - Investigation Performed (Root Cause Analysis) (Form DD:951 – Section 1)
  - Corrective/Preventive Action Identified/Agreed and Progressed (Form DD:951 – Section 2A initially then quality incident template CA/PA stages)
  - Corrective/Preventive Action Implemented and Effective (Completion of Department Sign Off stage in template)
  - QA Final Review and Closure
  - Document actions or rationale for no requirement for Corrective/Preventive Action (Form DD:951 – Section 2B)

- **Start of Process**

  - Incident or Potential Incident Identified
  - If product/ component Related
  - Quarantine Product (When Applicable)
6.1 Documentation

6.1.1 This SOP will be complemented by documentation of the process using the Q Pulse quality incident wizard (for reporting) and the quality incident template for recording the outcome of various stages.

6.1.2 Additionally FORM:DD:949 ‘Problem Identification and Remedial Action’ can be used to report the incident initially where access to Q Pulse 5 is unavailable. The details from this form will be submitted to the RA&C Department, who will raise the incident via the quality incident wizard.

6.1.3 The investigative stage and CAPA identification stage is recorded on FORM:DD:951 ‘Investigation and Corrective Action’ or, in the case of investigation of platelets/blood components flagging positive on BacT Alert on FORM:DD:649 ‘Checklist For Treatment of Blood Components Giving a Positive BacT/ALERT result’.

6.1.4 In the event of a loss of Q Pulse for a period the following forms can be used to record the relevant details of the incident until Q Pulse is restored at which point the information contained in the forms will be used to update the incident on Q Pulse.

- FORM DD:950: Initial Quality Review
- FORM:DD:952: Follow Up and Effectiveness
- FORM:DD:953: Final QA Review and Closure

6.1.5 In all cases, responsibility for final approval of satisfactory completion of the incidents will rest with the Quality function specifically the Regulatory Affairs & Compliance Department

6.2 Summary of Procedure

6.2.1 The principle under which all incidents are recorded and managed is that they should be investigated primarily within the area of NIBTS where the incident occurred.

6.2.2 Incident should be reported using the quality incident wizard as rapidly as possible, at latest on the first working day after the incident being detected (as per SOP QS:018 Raising an Incident using Q-Pulse Quality Incident Wizard).

**Consideration must be given to the impact on any product and, where required, Recall initiated or product placed in quarantine.**

The incident should also be brought to the attention of the relevant Head of Department as soon as possible by the person detecting the incident.
6.2.3 **Scoring of Risk associated with Incident**

Regulatory Affairs & Compliance Department must record each incident and categorise for risk. Initial assessment of severity will be completed as soon as possible after the incident is reported. The categorisation will determine the level of follow-up required, these are detailed below.

Note when assessing impact/ severity, it is important that this is a measure of **POTENTIAL** risk of the incident, rather than risk specific to the circumstances investigated.

See appendix 1 for matrices to be used to assign risk level.

Please note any incident likely/ potentially able to cause death or serious harm to a patient/donor must be classed as a Red incident irrespective of scoring by this method.

On detection and during review/scoring of an incident the need for recall of blood components or pharmaceutical products should always be considered.

6.3 **Categories of Deficiency and Appropriate Response**

All deficiencies are classified as critical (Red), major (Amber) or other (Yellow or Green).

6.3.1 **Critical deficiency (Red Incident):**

An incident which has produced or leads to a significant risk of producing an outcome which is harmful to donors.

Any incident which has or could potentially cause extensive injury, major permanent harm or death must be classed as a Red incident irrespective of scoring on the matrix.

- Investigation must be initiated within 24 hours, involving all relevant individuals to discuss and agree any necessary actions. The minutes of such meetings will be retained within the Incident File.

- Full investigation should be completed within 10 calendar days with a target for closing out the incident (all CAPA completed and reviewed) within 30 calendar days.

- A formal review meeting must be held within 1 month. This review meeting will ensure that an action plan has been initiated and to examine root cause analysis. The date of this meeting should be agreed at time of initial discussions and added to Q Pulse as a corrective action.
• All category red incidents must be reviewed for the effectiveness of remedial action. This will involve a quality audit where appropriate, and review by the Incident Management Forum.

• Category Red incidents must be reported to the Chief Executive or Medical Director on the day of initial categorisation.

Note: With regards to all red incidents the RA&C Manager and Chief Executive or Medical Director shall decide what other members of the SMT and also if the board shall be required to be informed of the applicable incident

6.3.2 **Major deficiency (Amber Incident):**

An incident which has or may produce a component which has the potential to cause harm or a major deviation from EU GMP or the investigation of an ‘other’ incident leading to the discovery of several associated incidents.

• Investigation must be initiated within 2 working days.

• The investigation will include an assessment of Root Cause(s). However, this may not require a formal meeting. Full investigation will be completed within 10 calendar days, with a target for closing the incident (all CAPA completed and reviewed) within 30 calendar days.

6.3.3 **Other deficiency (Yellow/ Green Incident):**

A deficiency which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice. (A deficiency may be “other” either because it is judged as minor or because there is insufficient information to classify it as major or critical).

• Investigation must be initiated within 5 working days.

• The investigation will include an assessment of Root Cause(s). However, this will not require a formal meeting. Full investigation must be submitted within 15 working days, with a target for closing out the incident (all CAPA completed and reviewed) of 30 days.

Several related major or other deficiencies may be taken together to constitute a critical or major deficiency (respectively) and will be reported as such.

The procedure to follow if an incident investigation will not meet its assigned timeline of completion is highlighted in section 6.7.

Management and follow up of each incident will depend on the risk level assigned (red, amber, yellow or green). It is the aim of NIBTS that all incidents will have the root cause(s) assigned. The most serious incidents will be subject to review meeting during which root cause will be determined. For complex incidents, this may involve the use of root cause analysis tools to assist in determining root cause (see SOP:QA:110 Techniques to be Employed During Quality Investigations). Particular attention will be paid to category red incidents and recurring amber incidents.
6.4 Completion of Incident Wizard/Forms/Template Stages

6.4.1 Quality Incident Wizard or FORM:DD:949: Problem Identification and Remedial Action (All Staff)

As soon as an incident or potential incident is detected, it must be reported via the quality incident wizard – see SOP:QS:018 Raising an Incident Using the Q Pulse Quality Incident Wizard or if no access to Q Pulse is available on FORM:DD:949: Problem Identification and Remedial Action.

Consideration must be given to the impact of the incident on the quality or safety of blood or blood products and if required a recall initiated and/or product placed in quarantine.

The method for reporting incidents is as follows:

6.4.2 Initiation of the Wizard or Form

The person making the initial observation must immediately log the incident using the Q Pulse wizard or FORM:DD:949: Problem Identification and Remedial Action.

To ensure full traceability, it is important that all relevant information is given by fully completing all mandatory fields in the wizard or relevant sections of form. This will assist thoroughness and timeline of any investigation to be carried out:

- Date and where applicable time of incident discovery
- Location/Department/Section in which the incident occurred
- A full description of the incident, including but not limited to;
  - Details of unit/lot numbers of the component(s) or product(s) involved, together with associated materials, kits etc.
  - Details of procedure, process or service including SOP numbers
  - Details of personnel, staff or public who are involved (using Staff grade/department; Donor Number; H&C Number to identify)
  - A legible summary of the incident is required: where applicable, identification of any relevant equipment/instrument involved
  - If FORM:DD:949 is being used, the person raising the Incident shall then print/sign their name, as well entering their department and the date.
- Details of remedial action taken to correct problem and to prevent a recurrence of the incident (minimise risk/mitigate the immediate effects of the non-conformity or achieve short term benefits)

If using FORM:DD:949, the person taking the remedial action shall sign print/sign their name as well entering their department and the date on completion of the remedial actions.
Ensure Department Manager or deputy is informed of the incident

All sections/fields must be completed. Any missing information may result in a delay in the completion of the report. This could lead to a further delay in review and decision to release/discard any associated components or products.

If using FORM:DD:949 the original form should be submitted to the Quality Department and arrive as rapidly as possible and, in all cases, within 2 working days of the incident being detected and of the report being initiated. Any incident considered to have serious potential adverse effects must be communicated to the Head of Department and RA&C Department as soon as possible if there may be a delay in delivery of FORM:DD:949.

6.4.3 Initial Quality Review (RA&C Department)

On receipt of the incident report the RA&C will carry out the following actions and populate the relevant sections of the quality incident template on Q Pulse 5 as per SOP:QS:017 Use of the Quality Incident Template.

6.4.3.1 Carry out the initial categorisation of the incident and assign the appropriate category (Red, Amber, Yellow or Green), using the criteria contained in appendix 1.

Scoring of the incident is based on severity or potential severity, the likelihood of recurrence, and detectability of the incident. Note the severity of an incident may be re-graded as evidence is uncovered during investigation. Permission must be obtained from the RA&C Manager, who will document the reasoning for the change of grading in the notes section of the NC on Q Pulse 5.

Category Red incidents must be reported to the Chief Executive or Medical Director on the day of initial categorisation.

Note: With regards to all red incidents, the RA&C Manager and Chief Executive or Medical Director shall decide what members of the SMT (and also the Board) shall be required to be informed of the applicable incident.

6.4.3.2 If remedial action has been carried out to contain the incident, Heads of Department implicated and RA&C Manager/ Deputy will assess the remedial actions taken, and determine if appropriate. Approval of actions taken is recorded on Q Pulse.

If actions have been determined not appropriate, propose further actions necessary to prevent a recurrence, including the person responsible and the date of completion, and record on Q Pulse.
6.4.3.3 Where an incident involves components, products, or cord blood donations the impact on product quality and patient safety must be considered. The fate of the component, product or cord blood must be decided, where appropriate the Responsible Person and Designated Individual approve the decision.

6.4.3.4 Where it is decided that the incident requires other related components, products, cord blood to be recalled or pharmaceutical products, this should be initiated using the procedures defined in SOP:QA:002 Blood Component/Product Recall Procedure or SOP:QA:102 Procedure for Recall of Pharmaceutical Products

6.4.3.5 Where it is decided that an incident constitutes a “serious” adverse event, reaction or incident, the incident must be notified to the Regulatory Affairs & Compliance Manager, Chief Executive and/or the Medical Director or assigned deputy, a decision will then be made whether a SABRE report must be made (SOP:QA:079). SABRE reportable incidents must be reported, with associated evidence attached to Q Pulse, within 2 days of the incident being raised. Initial reporting should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information. The severity of an incident may be upgraded as evidence is uncovered during investigation (see 6.3.2.1): If this necessitates reporting to SABRE at a later date, details must be included in the note added to the NC on Q Pulse.

If the serious adverse event involves tissues or stem cells then the Designated Individual for the tissue establishment will decide whether a report must be made to the Human Tissue Authority (SOP:QA:092 - Reporting Serious Adverse Events or Reactions to Human Tissue Authority ). The Chief Executive will decide if onward reporting to other bodies such as Northern Ireland Adverse Incident Centre, Health and Social Care Board) and/or other blood transfusion centres as necessary.

6.4.3.6 In agreement with the Departmental Manager or deputy of the area affected, an investigator will be assigned, who will be responsible for leading the investigation and determine any corrective actions required.

The person assigned to carry out the investigation will use FORM:DD:951 Investigation and CAPA (or FORM:DD:649 for bacteriology positive results) and will liaise with RA&C Department and any other applicable departments throughout the course of the investigation.
6.4.3.7 If required the relevant personnel, judged to need to know of the incident, will either be informed by adding an action to the relevant template stage which will result in the generation of an automatic e mail or if these individuals do not have Q Pulse access via e mail or forwarding photocopies of the relevant information. This may include:

- Relevant Senior Manager(s)
- Relevant Head(s) of Department.
- Any other relevant personnel e.g. Information Governance Officer if related to loss of or unauthorised access to data or records

The distribution of the copies must be carried out as soon as possible after the incident has occurred.

6.4.3.8 Should the problem/issue be rejected the Originator has to be informed to why and the reason using the notes facility of Q Pulse. The process is then deemed closed.

6.4.4 FORM:DD:951: Investigation and Corrective/Preventative Action
(Assigned Investigator)

6.4.4.1 RA&C Department will prompt the assigned investigator by email to retrieve FORM:DD:951 from Q Pulse, for co-ordinating the investigation of the incident. A target date for completion of the investigation will be allocated and will be determined based on the categorisation of the incident i.e. red/amber/yellow/green.

6.4.4.2 On receipt of FORM:DD:951: Investigation and Corrective/ Preventative Action, the person assigned to carry out the investigation shall include the following steps:

- Provide details of any relevant information which has come to light during the investigation.
- In a clear and concise manner document what was considered during investigation and ruled in or out as a causal factor in the incident
- Identifying the root cause or events which identifies the source of the Incident
- Data collected during the investigation may be referred to and attached to the investigation as appendices rather that duplicating within the DD951 document.
6.4.4.3 Refer to SOP:QA:110 Techniques to be Employed During Quality Investigation for guidance on investigation methods available.

Note: If the root cause has been determined to be “Human Error” the report must detail the reasons why the root cause has been deemed as Human Error and demonstrate that all other potential causes have been eliminated.

The root cause analysis is to identify “system errors” and provide learning points to improve practice; it is not designed to apportion blame to individuals.

If assistance is required regarding the most appropriate root cause analysis tools to apply contact the appropriate training root cause analysis expert within the appropriate department or contact the RAC Lead who will indicate the most appropriate expert.

6.5 Section 2: Corrective/Preventative Action

On completion of section 1 of FORM:DD:951: Investigation and CAPA, the investigator will then establish if there is a requirement for a corrective/preventative action plan which will be documented in section 2A of the form.

Corrective Action - Action to eliminate the cause of a detected non-conformity or other undesirable situation.

Preventative Action - Action to eliminate the cause of a potential non-conformity or other undesirable potential situation

If no corrective/preventative action is required then section 2B of the form will be completed, detailing the rationale to why no corrective/preventative action is required for this incident.

On completion of section 2A or 2B the form is then passed to the RA&C Department.

6.5.1 Section 2A Corrective/Preventative Action Required

Following the conclusion of the investigation/root cause analysis, the corrective action will be documented (including the responsibility and completion date) and the incident will not be closed until supporting documentation is provided to show that the corrective action was implemented.

The assigned investigator shall document/describe the Corrective/Preventative Action and establish Action Plan and timeframe for completion, and record on section 2A of FORM:DD:951 Investigation and CAPA. This may include modifying existing or creating new policies, procedures, instructions or work practices.
As part of the plan the following have to be documented:

- Propose the action to be taken
- Proposed implementation date
- The effectiveness criteria for the prescribed action
- Proposed effective date.
- The implementation date is the date when implementation of the action is to be completed. The effective date is the date that the action is considered to be effective.
- Record on the form if the actions will take time to introduce or which require resources or inputs from other Departments.
- The department manager or deputy shall review the Actions and established Action Plan and timeframes for completion and if required propose any further actions necessary to prevent a recurrence,
- Where a corrective action involves the initiation of a change the Change number (where available) should be logged along with the target date for completion of that change. It is acceptable to close the action upon raising of the change and agreement of the implementation date of the change, however the change must then be executed in the agreed timelines and any slippage brought to the attention of the RA&C Department.

On quality approval of FORM:DD:951 the RA&C Department will update the relevant stages of the quality incident template (as per SOP:QS:017) including the addition of the identified Corrective and Preventative actions.

Owners of the identified actions are required to complete the actions in the agreed timeframes and indicate completion by completing the action on Q Pulse and attaching any supporting evidence as per SOP:QS:017. Any slippage in completion should be notified to the RA&C Manager or Deputy with the associated reason and revised action target date. The completion of these actions will be tracked via Q Pulse.

6.5.2 Section 2B No Corrective/Preventative Action Required

If no corrective/preventative action is required, Section 2B of Form 3: Investigation and CAPA will be completed detailing a rationale to why no corrective/preventative action is required.
Prior to returning to RA&C, approval must be obtained from the Department Manager or deputy.
6.5.3  **Departmental Sign Off – Follow Up and Effectiveness Review**  
*(Department Manager or Deputy can be assigned)*

**Note:** This process/step is gathering the evidence, either copies of the data or reference to where it can be found (this will include reference numbers), to confirm all actions have been completed and are effective.

6.5.3.1 The person assigned to carry out the follow up and effectiveness review will use Departmental Sign Off Stage in the quality incident template to document the review.

6.5.3.2 The person assigned to carry out the follow up/effectiveness review shall include the following steps:

- Verifying the completion of the corrective and preventive action.
- Ensure the effectiveness of the actions are acceptable and if required determine any follow up actions.
- Where support data is available, evidence should also be provided to ensure the actions were effective.
- Review of the effectiveness can also be obtained by reviewing the incidents for reoccurrences.

**Actions deemed effective:**
If the action(s) are deemed to be effective, then complete the stage indicating this status.

**Actions deemed not effective:**
If the action(s) are deemed not effective in addressing the problem, then the reviewer meets with the person responsible for the action to re-examine the incident and both agree on an appropriate course of action and schedule for implementation and review. They must come to an agreement and the RA&C Manager or Deputy is informed. Any additional actions must be agreed and approved by the RA&C Department  

- Any supporting documentation will be attached to the incident template and any new actions added to the appropriate stages. Instructions re attachment of evidence can be found in SOP:QS:017.
- This will remain open until the effective actions can be demonstrated, on completion of the actions and confirmations of effectiveness the stage can be closed.
6.6 Final QA Review and Closure (Quality)

On receipt of FORM:DD:951 or completion of the Departmental Sign Off Stage, the RA&C Manager (or deputy) will carry out the following actions using the relevant fields/stages in the quality incident template:

- Organise a wrap up meeting with relevant personnel to discuss the follow up to amber or red incidents, if required.

- Ensure all relevant documents are attached to Q Pulse.

- Ensure the following fields are completed:
  - Source of Incident (record in fault category field)
  - Department Incident occurred
  - Root cause

- Review the categorisation of the incident based on the evidence gathered, and ensure that the correct category was assigned.

- Re-grading of an incident should be approved by the RA&C Manager, and an explanatory note added to Q Pulse, including the new scores for severity/ recurrence/ detectability.

- Ensure that any associated recall has been completed.

- Ensure any onward reporting has been completed and accurately and accurately documented in template i.e.

  - SABRE Reporting (guidance re criteria for reporting can be found on the MHRA website www.mhra.gov.uk)
  - HTA Reporting (guidance re criteria for reporting can be found on the HTA website www.hta.gov.uk)
  - Reports to Other Authorities e.g.
    - NIAIC (guidance can be found at www.dhsspsni.gov.uk/niaic).
    - HSCB (guidance issued by HSCB in Procedure for reporting and follow up of Serious Adverse Incidents April 2010)

  - Enter relevant details of onward reporting into the relevant electronic table held in the Onward Reporting Folder located within the Quality Incident Folder in the Quality drive on the NIBTS 1 network drive.

  - During the review ensure that if the incident has not been reported that and is then deemed to be reportable that the appropriate process (SABRE/HTA or other) is followed and the details are recorded on the form.

  - Receiving feedback from relevant review forum

  - RA&C Manager or Deputy will decide whether the actions(s) have been effective or whether there is a requirement for further actions.
Actions deemed effective:

- If the action(s) are deemed to be effective, then complete the remainder of the template and review all the stages/associated forms for completeness and accuracy and then close the incident.

Actions deemed not effective:

- If the action(s) were deemed not to be effective, insufficient or not completed, a new incident will be raised which will address the issues and this will remain open until the effective actions can be demonstrated.

- On completion of the above step the RA&C Department will review all stages/associated documentations for completeness and accuracy and then close the incident.

- Provide feedback to the originator on the final outcome of the Incident, this can be done by e-mail or face-to-face meeting.

6.7 Overdue Investigations/Actions/Incidents

6.7.1 Timeliness in initiating the investigation is essential to ensure an accurate and full gathering of information. Investigations for all incidents should be completed and returned within timelines detailed in section 6.3. All efforts must be made to complete the investigation within the assigned time, however where more time is needed to complete the investigation, this must be notified to the Head of Department/Deputy and RA&C Department Manager/Deputy using FORM:DD:1486 for the extension obtained, with justification for the extension and explanation regarding how any residual risk is being managed. A new target date for completion will be recorded. Extension will be granted by RA&C on the following basis:

- Appropriate levels of containment of incident are demonstrated
- All corrective / preventative actions have been identified and recorded.
- The reasons for the delay are justified.

The form will be scanned and attached to the investigation on Q Pulse.

6.7.2 Investigations will be tracked to ensure they do not exceed the target submission dates, this will be carried out by the RA&C department on a weekly basis and the investigator and department Head informed if they have exceeded the assigned time frame and completion of form DD1486 instructed. Failure to respond or inadequate explanation for the delay will result in escalation to the relevant SMT member and may necessitate the raising of a further incident.

6.7.3 Corrective/Preventative Actions will be tracked to ensure they do not exceed their target date, this will be carried out by the RA&C
department on a weekly basis and the investigator and department Head informed if they have exceeded the target date and completion of form DD:1486 instructed. Failure to respond or inadequate explanation for the delay will result in escalation to the relevant SMT member and may necessitate the raising of a further incident.

6.7.4 Incidents that are over the 30 days will be treated as serious and will be reviewed at the monthly incident management forum, with the SMT and Board. (Reference: POL:QP:003 - NIBTS Policy for Incident Management)

Interim measures can be put in place to close the incident and control the changes through the change control process. This can only take place if the root cause analysis has taken place and the corrective action plan has been agreed.

If this process is used there has to be clear link between the Incident and the change control with the incident detail being recorded (including the incident reference number) within the change control document.

6.8 Trending

If near misses and accidents are properly reported and investigated, and if the recommendations derived from the investigations are implemented, similar types of incidents should not recur. By performing a trending analysis, systemic issues can be identified and the overall effectiveness of the incident investigation efforts can be assessed.

Trends are reviewed, gaps in CAPA are identified and improvement plans are developed to prevent future occurrences.

6.8.1 Trending of the causes of incidents will be undertaken by a variety of means:

6.8.1.1 Incident Management Meeting:

At this forum, incidents will be discussed and any recurring themes highlighted and a further incident raised to allow a review of root cause and CAPA assigned to incidents within the trend by the department involved. This forum will allow the identification of both trends arising within departments and common trends manifesting throughout NIBTS.

6.8.1.2 Departmental Meetings:

Incidents relevant to the department will be discussed in detail at departmental meetings and any incidents with recurring themes highlighted. The Quality Representative at these meetings will decide if a further quality incident should be raised to deal with the trend
6.8.1.3 Via Q Pulse 5

Root causes of incident will be recorded into broad categories to assist the trending process described above.

6.8.1.4 Customer Complaints:

Quality incidents received from external customers of NIBTS i.e. Hospital Blood Banks, GPs etc will be trended separately by the Quality Department to assist in identification of areas for improvement.

6.8.1.5 Risk Management

To facilitate effective Risk Management procedures and compliance with relevant standards and relevant NIBTS policies the Business Continuity and Risk Manager will access the Incident Management Register and/or Q Pulse incident log. Trending will be completed on a Quarterly basis.
6.9 Definitions

Incident

An Incident is defined as “An event which is a significant deviation from the normal expectation of a particular part of the NIBTS operations”. All incidents must be recorded and reported so that effective action can be taken.

Root Cause

A root cause is the cause or causes that if addressed will prevent or minimise the chances of an incident recurring. Root cause analysis is a technique for undertaking a systematic investigation that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened.

Retrospective and multi-disciplinary in approach, it is designed to identify the sequence of events, working back from the incident. This allows the real causes of an incident to emerge so that organisation can learn and put remedial action in place.

MHRA -- Serious Adverse Reaction (SAR)

‘An unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity.’

MHRA -- Serious Adverse Event (SAE)

‘Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood products components by the blood establishment which may have an influence on their quality and safety.’

Health and Social Care Board (HSCB) -- Serious Adverse Incidents (SAI)

‘Any event or circumstance that could have or did lead to harm loss or damage to people, property, environment or reputation’ arising during the course of the business of a HSC organisation/Special Agency or commissioned service.

HTA – Serious Adverse Event (SAE)

“All untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells:- (a) might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions, or (b) might result in, or prolong, hospitalisation or morbidity.”
HTA – Serious Adverse Reaction

“An unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity”.

Corrective Action –

Action to eliminate the cause of a detected non-conformity or other undesirable situation.

Preventative Action –

Action to eliminate the cause of a potential non-conformity or other undesirable potential situation.

Remedial Action –

Action taken to mitigate the immediate effects of non-conformity.

NIAIC - Medical Devices

‘Medical devices and equipment are items used for the diagnosis and/or treatment of disease, or for monitoring patients, as well as aids for daily living.’

SABRE

Reports to MHRA are completed through SABRE, the MHRA on-line reporting system; reports to the HSSPS are completed using the current Circular.

6.7 LIMITATIONS OF THE EXAMINATION

Not Applicable.

7 RESULTS

Not Applicable.
**Appendix 1:**

*Matrices used to Determine Risk Related to a Quality Incident*

**RISK CRITERIA FOR IMPACT/SEVERITY (A)**

<table>
<thead>
<tr>
<th>Severity Score</th>
<th>NIBTS Objectives</th>
<th>Potential Harm to Patient / Donor</th>
<th>GMP Issues</th>
<th>Potential Product/ Component Loss</th>
<th>Reputation</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Catastrophic</td>
<td>Unable to function. Inability to fulfil corporate obligations</td>
<td>Extensive injury, major permanent harm, death *</td>
<td>Batch recall</td>
<td>Failure to supply</td>
<td>Highly damaging adverse publicity/ loss of public confidence</td>
</tr>
<tr>
<td>4 Major</td>
<td>Significant impact on service provision</td>
<td>Critical GMP infringement</td>
<td>Total loss of stock in one location</td>
<td>National adverse publicity major loss of confidence in organisation</td>
<td></td>
</tr>
<tr>
<td>3 Moderate</td>
<td>Service objectives partially achievable, over 3 days lost time RIDDOR incident</td>
<td>Medical treatment required. Semi-permanent harm up to 1 year. E.g. wrong component transfused, Non-compatible component issued</td>
<td>Major GMP infringement</td>
<td>Significant loss of stock in one location</td>
<td>Local adverse public embarrassment leading to limited damage. Local MP interest or legal implications.</td>
</tr>
<tr>
<td>2 Minor</td>
<td>Minor impact on service provision</td>
<td>More significant GMP infringement</td>
<td>Minor stock loss (few units or low proportion of batch)</td>
<td>Some public embarrassment</td>
<td></td>
</tr>
<tr>
<td>1 Insignificant</td>
<td>Minimal impact. No service disruption</td>
<td>No obvious harm/ injury</td>
<td>Very minor GMP infringement</td>
<td>None/ minimal stock loss (max 2 components)</td>
<td>No interest to the press or public</td>
</tr>
</tbody>
</table>

* Please note any incident likely/ potentially able to cause extensive injury, major permanent harm or death must be classed as a Red incident irrespective of scoring by this method.

**RISK LIKELIHOOD/PROBABILITY ASSESSMENT (B)**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Score</th>
<th>Expected Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain</td>
<td>5</td>
<td>More than 75% chance of re-occurring</td>
</tr>
<tr>
<td>Likely</td>
<td>4</td>
<td>50% - 75% chance of re-occurring</td>
</tr>
<tr>
<td>Possible</td>
<td>3</td>
<td>25% - 50% chance of re-occurring</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
<td>5% - 25% chance of re-occurring</td>
</tr>
<tr>
<td>Rare</td>
<td>1</td>
<td>Less than 5% chance of re-occurring</td>
</tr>
</tbody>
</table>
The RISK SCORE (AxB) shown in the table below. The Risk Score is from 1 to 25.

<table>
<thead>
<tr>
<th>Insignificant</th>
<th>Minor</th>
<th>Moderate</th>
<th>Major</th>
<th>Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Likely</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>Possible</td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Rare</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

The Risk score is entered in the table below, to obtain Risk Level (C).

**Detectability**

Detectability is the ease with which a failure will be detected before the impact of the failure to the system or process being evaluated is detected i.e. what mechanisms are in place (if any) to detect a failure if it were to occur.

<table>
<thead>
<tr>
<th>Description</th>
<th>Criteria</th>
<th>Value (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High degree of detectability</td>
<td>Controls/Steps in place will detect</td>
<td>1</td>
</tr>
<tr>
<td>Good Detectability</td>
<td>Controls/ steps in place likely to detect</td>
<td>2</td>
</tr>
<tr>
<td>Likely to Detect</td>
<td>Controls/ steps in place may detect</td>
<td>3</td>
</tr>
<tr>
<td>Fair Detectability</td>
<td>Controls/ steps in place unlikely to detect</td>
<td>4</td>
</tr>
<tr>
<td>Low or no Detectability</td>
<td>No ability to detect</td>
<td>5</td>
</tr>
</tbody>
</table>
To ensure it has been carefully considered we take the Risk Level (C) from table above and multiply it by the Level of Detectability (D).

<table>
<thead>
<tr>
<th>Risk Level (C)</th>
<th>Most Detectable 1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Least Detectable 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extreme Risk</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>High Risk</td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Low Risk</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

C x D = Final Risk Score after Detectability. This final risk score after Detectability will be converted to the Final Risk Level after Detectability.

<table>
<thead>
<tr>
<th>C x D Final Risk Score</th>
<th>Rating</th>
<th>Final Risk Level after Detectability</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Extreme Risk</td>
<td>4 (Red)</td>
</tr>
<tr>
<td>8-12</td>
<td>High Risk</td>
<td>3 (Amber)</td>
</tr>
<tr>
<td>4-6</td>
<td>Moderate Risk</td>
<td>2 (Yellow)</td>
</tr>
<tr>
<td>1-3</td>
<td>Low Risk</td>
<td>1 (Green)</td>
</tr>
</tbody>
</table>