APPENDIX 1: DETAILS OF EXTERNAL INSPECTION OUTCOMES

January 2015

- No inspections in January

February 2015

- **CPA – IBGRL 13th February 2014**
  - **11 Others**
    - The management meeting minutes do not have agreed timeframes for completion of actions. There was little evidence from subsequent meetings to demonstrate whether these actions had been discharged.
    - The latest version of the Quality Policy has not been authorised by the Laboratory Director. Although this was only a point change to the version, this included additional scope to the service.
    - The laboratory is offering a RHD & RHCE gene sequencing service. The validation for this stipulates 12 repetitions but at the time of the assessment only 6 had been performed and the validation was therefore incomplete.
    - The reports for the high throughput RhD negative testing and the RHD & RHCE gene sequencing did not contain the sample type.
    - Controlled documents do not contain the name of the authoriser.
    - There was no user or patient information for the high throughput RhD negative testing. This test is currently offered to local users.
    - Although there were comprehensive records of initial training and competency there is no formal documented method for how competency is periodically reassessed. In practice a number of methods are used to monitor on-going competency, but these are not formally documented.
    - The Health and Safety Manual MPD1017 states the laboratory has an H&S Manager, GM. In reality GM is the H&S Co-ordinator and there is no description of this co-ordinator role in the H&S Manual.
    - There is no genetic IQC (e.g. running a mutant control) for the RH gene sequencing.
    - SLA for laboratory services provided to users in the Republic of Ireland were not available at the assessment.
    - The Control of records procedure states that worksheets are kept until the final report is authorised. In practice these are kept for 30 years.

March 2015

- **MHRA Leeds – 17th – 19th March 2014**
  - **3 Others**
    - QMS : Event investigation, CAPA implementation, Change control not raised
    - Temperature: validation & monitoring of storage, equipment and facilities

- Control of Documents: Document reviews not completed, overwriting on temperature log

- **MHRA Colindale – 27th March 2014**
  - **1 Major**
    - Temperature monitoring and control: 17 items of inadequate validation & monitoring of storage, equipment and facilities
  - **6 Others**
    - QMS: Event management
    - Evaluation of donors: Heart rate measurement, Booth confidentiality, screening prompts
    - Documentation deficient: Procedure for application of Lidocaine, record overwrites, missing entries, no record of a vehicle check
    - Control of Change: non-contemporaneous record completion, extension of target date with no permission
    - Facilities and equipment: Cleaning ineffective
    - Control of training and related records: training of procedures post effective date, licence checks for drivers not completed

- **MHRA, Brentwood 30th – 31st March 2014**
  - 2 Others
    - Trolleys in cold room with wooden bases
    - Internal doors damaged, no interlock system between GMP area and external area

- **HTA - Royal Orthopaedic Hospital Satellite site 19th March 2014**
  - 1 Advice and Guidance
    - Based on current activity, the DI may wish to consider rationalising the activities for which the establishment is licensed. The DI should notify the HTA if changes to the license are necessary.

- **HTA – Colindale 11th March 2014**
  - 1 Advice and Guidance
    - The establishment distribute UCB and Leukocytes for research on a daily basis. Although it is not possible to retain individual donor identification due to the high throughput nature of cone filtration, the DI is advised to ensure that a high level of traceability of the research material is maintained.

- **HTA – Sheffield 4th March 2014**
  - Awaiting report

- **HTA – Filton 24th - 25th March 2014**
  - 2 Advice and Guidance
    - 1. Although the establishment conducts monthly audits of records, a number of minor inconsistencies were noted when reviewing the processing records, such as: Omission of information relating to seal tag number on issued products. Method of transfer of product, for example dry shipper or room temperature transfer. Some checklists had additional, manually added fields by the person completing these

checks, such as ‘any adverse events’. The DI is therefore advised to review the scope/wording of the existing audit checklist and to update forms to ensure that they reflect practice.

- The DI is advised to review the approach to the completion of environmental monitoring records to ensure there is a consistent, agreed approach to room designation during the period of monitoring, either ‘at rest’ or ‘in operation’. The basis for designating a room as ‘at rest’ or ‘in operation’ should be documented.

October to December 2014

- **CQC - Liverpool Donor Centre and Cheshire, Staffs and Mersey, October 2014**
  - Meets requirements

- **Underwriters Labs - Reagents, Liverpool October 2014**
  - 1 Comment

- **HTA – Southampton, November 2014**
  - 4 Comments

- **EFI - Colindale December, 2014**
  - 2 Others

July to September 2014

- **Colindale National Bacteriology Laboratory, Audited by CPA (ISO15189) July 2014**
  - 5 Others

- **Liverpool MHRA August 2014**
  - 2 Others
  - 2 Comments

- **Liverpool MS and IMP, August 2014**
  - 7 Others
  - 3 Comments

- **HTA Satellite sites**
  - 9 Advice and Guidance

April 2014 to June 2014

- **MHRA CBC, April 2014**
  - 1 Major
    - A change control was not raised for the removal of piece of equipment (light inspection viewer) from the clean room into the QC laboratory. Three other Change controls were reviewed and found to be lacking small pieces of information.

- 4 Others
- 5 Comments

- **MHRA Southampton, May 2014**
  - 6 Others
  - 2 Comments

- **HTA, Liverpool, June 2014**
  - 3 Advice and Guidance

APPENDIX 2: QUALITY ACTION PLAN

1. Cultural behaviour - To support the organisation in achieving its ambition of zero major non-compliances at external inspection and to have systems in place to ensure that this is sustained.	
Reason for change	**One of the key areas where we must improve is in following our own procedures correctly at all times. Staff at all levels across the organisation must fully understand and deliver on the key area of personal accountability and responsibility to follow good practice in their area of work. This will reduce adverse events and ensure that we put patient and donor safety at the heart of everything we do.** **Over the next 2-5 years, leaders in all areas of the organisation must take action to reinforce key messages about following good practice within their teams. With the support of the QA Department, senior managers must take a lead in the areas for which they are responsible.** **This improvement is necessary if we are to achieve a permanent state of inspection readiness and ensure patient and donor safety.**

Key actions	Example actions	Outcome/Benefit
Develop a plan to enable staff to understand their role, responsibilities and what they are accountable for to deliver patient and donor safety. Ensure that staff understand the rationale of their actions by delivering the message of “why” along side the “what”.	• Organisation wide delivery of key messages at induction both corporate and local • Regular education regarding good practice for staff that is tailored to their business area • Ensure that we explain the “why” alongside the “what” in our training and education • Enhance communication of how we work with colleagues across	• Staff will understand why they are asked to perform a procedure in a certain way, working within the Regulatory framework and ensuring donor and patient safety. • Added resource due to less time spent dealing with mistakes • A better approach to inspection • Improved understanding of good practice and direction for all staff that is meaningful not generic • Improved accountability, not following procedures is unacceptable

Key actions	Example actions	Outcome/Benefit
	other directorates to deliver donor and patient safety • Job descriptions and PDPRs to have clear objectives related to good practice, improvement and expected behaviours • Agreed ways of dealing with poor responsibility and accountability performance	
Develop a more effective training and competency assessment of staff	• Review existing training and improve where necessary using training tailored to individual needs. • Ensure training includes the “why” alongside the “what” • Regularly assess competence • Review resourcing and roles for training delivery and also methods of delivery	• Reduced risk to patient and donor safety • Improved staff morale • Ongoing assurance that staff training is relevant and effective • Confidence that poor training is not the root cause of poor quality
Build on existing relationships with regulatory and accreditation bodies	• Develop a close working relationship with Regulators where future plans are shared and discussed • Arrange reciprocal visits for shared learning • Clarify and regularly review scope of inspections/visits	• Always be prepared for audit and inspection • Increase confidence regarding inspection for all involved • Build a culture of no surprises
Develop our Human factors capabilities to improve our effectiveness in areas such as root cause analysis (RCA), process design and process redesign.	• Run a workshop which further introduces Human Factor (HF) tools into the organisation. • Develop and deliver training and awareness for staff on HF • Implement HF tools within root cause analysis, continuous	• The organisation will have better designed processes which accommodate HFs • Reduction of errors • Improve the effectiveness of root cause analysis and reduce recurrence of incidents.

Key actions	Example actions	Outcome/Benefit
	improvement activities and transformational change projects.	

2. Continuous Quality Improvement - To lead and support the transition from a regulatory compliance driven culture to one of continuous quality improvement, with clear focus on patient and donor safety, customer service and efficiency.	
Reason for change	**A culture of continuous improvement in the organisation must become a way of life. A focus on patient and donor safety and improving our customer service will improve compliance with the regulations and NHSBT quality management system.** **To support this, the QA team will continue to develop the Quality Management System to make it more streamlined, efficient and fit for purpose, therefore freeing capacity for both the QA team and its stakeholders.**

All areas of the organisation to work in partnership to use established and new continuous improvement methodology to make process improvements	• Work with the continuous improvement team to ensure best use of their resource through out the organisation • Knowledge sharing of continuous improvement with other organisations • QA Directorate to further develop their skills in continuous improvement • QA Directorate to further implement continuous improvement into their processes and into the NHSBT quality management system.	• Reduced complexity of systems • Better staff engagement in the designing systems and processes • Improved customer satisfaction • Reduced waste in our systems

All areas of the organisation to identify gaps in knowledge and understanding and to know what is needed to prepare for the future	• Improve NHSBT's understanding of the legislation and compliance through education and training • Incorporate the use of alternative tools, such as Agile to deliver change • QA team to work with the Regulators to identify an early warning system for potential changes to Regulations and to ensure that NHSBT have early sight and input into proposed changes • Implement the changes in collaboration with staff	• Improved external inspection performance • Improved business opportunity • Improved planning of changes and implementation of change
Review the current NHSBT document control system for compliance and ease of use. Benchmark our system against other similar organisations. Ensure we review systems in place within current market leaders both NHS and private.	• Perform a formal review of the current NHSBT document management system • Involve staff from all business areas • Visit and gain insight into what other companies are currently using that reflect the safety ethos of NHSBT. • Link to human factor work on suitability and usability of documents	• Potential to reduce the number of documents in place • Ease of use of documents for staff • Potential to reduce errors by having user friendly documents which staff are encouraged to use • Potential to reduce time spent in the management of the document management system by QA and the business
Investigate ways of making the IT systems that support patient and donor safety more efficient and user friendly	• In line with the current ICT Strategic Framework review current IT systems in all areas of the organisation to see how efficiency can be improved and have a positive impact on regulatory compliance and customer service	• Direct entry of data in QPulse • Reduced risk of transcription errors • Regulatory compliance with Data Integrity requirements.

	• Evaluate current IT systems with their compliance with Data Integrity • Ensure the process for the introduction of new IT systems/software are assessed for their compliance with data Integrity.	
Improve systems which have been identified as complex or causing efficiency and/or compliance issue for staff	• Review systems using CI techniques and identify and implement improvements • Examples – temperature mapping, task based training	• Greater levels of compliance • Improved efficiency levels

3. Leadership capabilities - To support the further development of Leadership and Organisation Learning and lead all NHSBT staff in understanding the impact their work has on donor and patient safety.	
Reason for Change	**All staff need to understand the potential consequences of poor practice on donors, patients and customers. This requires strong leadership from the Board, Executive Team and the NHSBT Leadership Team to communicate standards and support staff at all levels.** **One of the key areas we need to improve is the sharing of lessons learnt following adverse events or an inspection finding. This is required to reduce the likelihood of similar incidents happening in another part of the organisation. Sharing these lessons will facilitate continuous improvement.**

Key actions	**Example actions**	**Outcome/Benefit**
Leadership teams to support Good Practice as key to patient and donor safety by: • Leading on a message of donor and patient safety as main	• Leadership teams to develop appropriate training and 'inspection ready' initiatives and a structure for sharing these • Continue the programme of site	• Recognition by everyone of their role in ensuring patient and donor safety by following Good Practice • Improved learning and reduced incident numbers

Key actions	Example actions	Outcome/Benefit
driver of all roles within NHSBT • Giving strong and consistent messages on the requirement for compliance to regulations and QMS • Communicating the organisational ambition for zero major findings at regulatory inspections	briefings delivered by key leaders • Ensure that the learning from incidents is shared with all appropriate areas so staff understand the events and their implications.	
Directorate leadership teams to take a lead on the management and closure of overdue events and document review.	• Overdue events are discussed at SMTs with clear ownership for management and closure identified. • Leaders within each functional area promote the benefits of ensuing that our QMS is robust and compliant by: ensuring document review/change control is performed in a timely and productive manner. • Zero tolerance of overdue issues is implemented	• We are currently at significant risk with our regulators in this area; leading and managing these areas may prevent a non compliance from our regulators. • SMART management of incidents and their closure will save time and resource.
Leadership Team to lead effective workplace walk rounds/visits, including through 'Connect to a region'	• Schedules in place and followed • GEMBA walks routine • Responsible Persons and Person Designate visits where appropriate	• Improved staff engagement • Greater visibility of and access to Senior staff • Leadership Teams have a better understanding of processes and issues
Strengthen partnerships between QA and Leadership teams	• Review the QA structure to establish if it is able to best support organisational needs • Review Management Quality Review processes to ensure there is appropriate feedback on	• Joint working to improve QMS performance • Greater understanding of business and QMS needs • Recognition of each others performance measures

Key actions	Example actions	Outcome/Benefit
	performance at SMTs and operational staff • Explore opportunities/options for improved working partnerships	
Improve shared learning across sites and directorates • in response to external and internal inspection findings • following critical/major adverse events	• Introduce more systematic approach to shared learning • Continue to identify trends in adverse events and produce action plans to prevent problems escalating • Apply and share the learning from external interactions, e.g. with other similar organisations such as other Blood services.	• Reduced repeat findings at inspections • Reduced risk of critical/major adverse events and therefore reduced risk of harm to patients and donors • Prevention of incidents rather than corrective action.

APPENDIX 3: SCHEDULED AND ANTICIPATED EXTERNAL INSPECTIONS – 2015/16

	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15	Jan-16	Feb-16	Mar-16
Leeds								HTA				
Liverpool							UL					
Liverpool ATU												
Manchester/Lancaster	MHRA											
Newcastle						EFI					MHRA	
Sheffield							MHRA	JACIE				
Brentwood												
Cambridge		MHRA										
Colindale												
NBL (Colindale)												
NTRML (Colindale)												
Tooting				MHRA								
Birmingham	HTA 8th							MHRA				
Filton				MHRA						FACT		
IBGRL (Filton)											UKAS	
Oxford	HTA 2nd JACIE			MHRA								
Plymouth			MHRA									
Southampton												
RCI (Birmingham; Colindale; Filton; Leeds; Liverpool; Newcastle; Sheffield; Tooting)					UKAS							
H&I (Birmingham; Colindale; Filton; Newcastle; Sheffield; Tooting)							UKAS					
Cord Blood bank (Colindale and Filton)										FACT		
CBC	MHRA											
ODT next due July 2016												

APPENDIX 4: DETAILS OF MHRA SABRE REPORTABLE EVENTS

January 2015 to March 2015

1. **Colindale -** Three units were cross matched for a named patient by RCI and all were found to be compatible. Only two were required and the additional unit should have been returned to stock. The hospital received one unit labelled as compatible for the named patient and one not labelled as compatible (as the wrong unit had been returned to stock). This resulted in the additional unit being issued to another hospital still labelled as compatible for another patient.

2. **Newcastle** - 34 units of red cells were not placed in 4°C storage within 27 hours of venepunture.

3. **National** - Recall failures. Review of failures for 2014 shows a low level, but persistent occurrence of recall failures. This NQI is to help manage changes and improvements to the recall system.

4. **Colindale** -Sample numbers were switched for samples being tested for feto maternal haemorrhage during loading onto the flow cytometer. This resulted in the results being assigned to the incorrect samples and reported to the hospitals.

5. **Southampton** - Hospital was issued with a red cell pack with a radsure label indicating it had been irradiated but it did not go through the correct pulse stages. Therefore, the product description was red cell in additive solution not irradiated as it should have been. Unsuitable units received for transfusion.

6. **Filton** - Platelets sent to Southampton were packed using cooled phase change material instead of warm phase change material. 43 units were implicated.

October 2014 to December 2014

7. **Filton** - Unit of red cells issued to hospital as S- for a patient with anti-S. Subsequent compatibility testing by the hospital pre-transfusion, showed an incompatibility. Subsequent testing by RCI Reference, found the unit we had issued to be S+.

8. **Colindale** - A report was issued to a hospital which reported incorrectly the antibodies detected as anti-Lua+anti-Lub instead of anti-Lea+anti-Leb. Hospital informed RCI of the error.

9. **Filton/ Colindale** - Microbiology Repeat Reactive Recall initiated by Testing on 20/10/14. The pooled cryoprecipitate had been issued to a hospital. Brentwood used to be issuing site for hospital but changed to Colindale. No response received when recalls checked on 30/10/14. Recall not actioned by either site.

10. **Colindale** - Mis-link with donor with same name and DOB but different address. The error was picked up at Testing Filton due to ABO incompatibility.

11. **Filton** - On 13/11/14, it was identified that a BacT recall from 22/10/14 was not actioned at the time of notification by Alarm point. The paperwork for the recall could not be found in Hospital Services or Quality Assurance at Filton. There are no records of the implicated units being returned and no email to the TM office at Colindale informing them that the units have been transfused. Tooting Hospital Services cannot find any paperwork for the recall and no email copy of the recall paperwork either. Pack 1 was issued to St Thomas Hospital on 19/10/14 and pack 2 issued to Poole Hospital on 21/10/14.

12. **Leeds** - Pooled platelet pack has been issued to a hospital when a constituent donation was unsuitable. Adverse event form (FRM1) received in QA stating that the donation had been bled into a BAT pack instead of a TAT pack due to the donor taking Ibuprofen the day before. Incorrect pack use had been identified at the session, but when QA checked the donation on Pulse, it had been issued to a hospital as a pooled platelet.

13. **Filton** - Upon unloading of bottles at the end of the 6 days of testing on the BacT/Alerts it was noticed that the aerobic bottle of a donation had not been inoculated with platelet sample. The anaerobic bottle of the pair had been inoculated with the appropriate volume, as had the pair of bottles from the associated pack 2.

14. **Newcastle** - A blood leak was found on a heat sealer on pod B during its first line clearance. The leak was discovered before commencement of processing.

15. **Tooting** - Incorrect unit recalled. Staff attempted to recall the previous bled donation instead of the present donation.

16. **Leeds** - 59 minutes into the procedure, machine alarmed, centrifuge spill, blood spill. Cells not returned to the donor. On inspection the bottom collar was leaking and the plastic cover had half sheared off. Full single platelet donation collected. Hold not placed on product at session, product issued.

17. **Filton** - New donor tested negative for sickle. However, sample was re-tested and was then found to be sickle positive. The batch kit being used was previously returned due to weak results. The company who provides the batch kits sent another batch of this weaker lot and there is currently no requirement to perform batch acceptance testing for this control.

18. **Filton** - Maternal plasma tested for foetal Kell status on samples on 2 separate occasions. Both samples were reported as Kell negative. The baby has been born and was Kell positive, showing our reported results were false negatives. A look back at all Kell assays from the beginning of the year showed that the diluted Kell positive control was outside the range of control value stated in SOP for a period of 22 days.

July 2014 to September 2014

19. **Leeds – Sheffield Manufacturing**. Leeds Nuffield hospital returned a platelet component for investigation after finding a large clump in the component on

receipt. Initial results from National Bacteriology Laboratory (NBL) indicate a positive bacteriology result. PULSE shows routine bacterial screening result as negative for this pack.

20. **Lancaster** - **Hospital Services**. Recall initiated for a platelet. Hospital notified about a platelet recall by telephone and advised that a fax would be received. The hospital member of staff that took the telephone call then forgot to check the fax and this was found 5 hours later. The platelets were in stock at the time the recall was initiated but had been issued and transfused by the time the fax was discovered.

21. **Sheffield** – **Processing**. Bacterial screening of platelets. The aerobic bottle did not have product inoculated into it.

April 2014 to June 2014

22. **Brentwood** - Whilst checking request management, it was noted that a Basildon order had been sent to the hospital without being dispatched on Pulse. Operator tried in error to dispatch the order, at this point a message appeared on screen stating "platelet on hold and could not be dispatched". It was identified that the unit was a Bacti recall. This incident has been X referenced with INC48950 raised by Filton as it was a similar incident.

23. **Filton** - **Bacterial Screening**. BacT/Alert system 4, module 4 was alarming and showing 4 positives (this subsequently rose to 83). Drawer 80 was found to be slightly open but there was no associated error for the open drawer.

24. **Filton** - **Bacterial Screening**. Donation turned positive at 03:15 on 16/02/14. This was acted upon when BacT staff arrived in the morning. On 17/02/14 Hospital Services found the bottle and paperwork, but had no notification of the donation turning positive. Upon investigation it was discovered that the positive result had not gone through Pulse correctly. This was corrected at 10:33 on 17/02/14. The platelet pool had been issued to Swindon hospital and transfused.

25. **Plymouth Hospital Services** - A platelet that had been returned to stock following a delivery error was re-issued before it was realised that it should have been quarantined (the box had a non-NHSBT cable tie indicating it had been opened). Recall was instigated but due to the delay the platelet was transfused. However there was no patient impact.

26. **Newcastle RCI** - Sample was accepted for cross matching by RCI on Call BMS, even though the demographics on the sample were not acceptable as per sample labelling procedures within MPD637. Blood was issued but an error was identified by the Reference Lab Manager whilst performing next day post On Call checks. The Hospital was contacted and the blood had not been transfused (a correctly labelled unit was taken when out patient arrived).

27. **Southampton Hospital Services** - Dose map produced to the new enlarged dimensions failed, this was identified before sending the map report to Public Health England. This resulted in a broader issue with irradiator mapping which has

been raised as a national quality incident which is still being managed to conclusion.

28. **Tooting Transport** - Mechanical failure of an NHSBT vehicle (and hence the refrigeration) that was carrying 58 units of RBCs, one box of platelets and 3 boxes of FFP on route to 3 hospitals The RBCs were discarded and the FFPs and platelets returned to stock. No patient impact as the units were stock items for the hospitals.

29. **Manchester Collections** - A further incident of suspected tampering with blood packs has been reported. These incidents involve breaking of cannulae and from evidence previously reviewed, it is believed that this could only have been caused by deliberate intent and are not pack defects. Four units sent for analysis, though 8 potentially implicated. Linked to previous occurrences of broken cannulae: INC40994, INC47202 and INC49341; and previous occurrences of cut tubing: PD/5211, PD/5212, PD/5213 and PD/5336. This event is now under investigation by the Police.

APPENDIX 5: DETAILS OF HTA REPORTABLE EVENTS

January 2015 to March 2015

1. **Southampton** - The patient details of an allogeneic patient have been overwritten with an autologous patient details. The original donor links of the potential donors and H&I testing for the allogeneic patient are still in place. The allogeneic patient had a transplant request created by Southampton SCI using patient and donor details already present on Hematos, the correct donor details were linked and cells have been transplanted. The autologous patient was new and cells have been stored with the correct details.

2. **Birmingham** - Cord collection received by SCI from Birmingham Heartlands Hospital (BHH) for processing was not procured under a valid HTA licence for that activity. Arrangements had been made by NHSBT for Phlebotomy UK Ltd (PUK) to collect this harvest under the existing Third Party Agreement (TPA) held between them and the NHSBT. This was communicated to the delivery unit in advance of the due delivery date. On 19/02/15, PUK contacted SCI to enquire about the delay since they had been contacted to attend collection which was the first indication to SCI that the collection had not been performed by PUK.

October 2014 to December 2014

3. **Colindale. Cord Blood Bank**. A courier turned up at St Georges Hospital (SGH) 18:15 to collect a consignment. The consignment which contained a cord blood unit and the accompanying paperwork (Collection Record) was handed to him. The courier signed the log of pickup (FRM3171), and CBB staff signed his PDA. The courier then left. Shortly afterwards the TNT courier arrived to collect the consignment. CBB staff explained that it had already been collected, at which point TNT informed CBB that it was not one of their staff who previously attended.

4. **Tissue Services** - Microbial contamination confirmed in two Batches of TBIS, a batch of Glycerol and a batch of skin Cryomedium supplied recently by Source Bioscience.

5. **Southampton - SCI** - 24/10/14. Clean room failure, room pressures went into negative pressure and vinyl wall and ceiling coverings have been pulled away from the walls/ceilings throughout the clean room suite. No alarms were triggered on the EMS.

July 2014 to September 2014

6. **Filton - SCI.** 20/06/14 Patient received stem cells from the wrong donor. A 4 year old with osteoporosis, had a previous stem cell transplant from father aged 1. A second transplant from an unrelated German donor was performed in January 2014 because of graft rejection. Stem cell top up was planned for 20/6/2014 because of gradual loss of the second graft (37% myeloid chimaerism). Stem cells from the German donor were requested by UHB. The incorrect stem cells from the father were supplied and reinfused. The error was detected on 30 July 2014 following enquiry about T cells for consideration of DLI, when it was discovered that products in stock did not correspond to what the clinicians at UHT were expecting.

7. **Southampton – SCI** - Tc-T issued to patient 19/08/14. T cell dose 5x10^6/kg. As the patient required 2x10^6/kg T Cells, instructions were issued to infuse only 8mls of the product. On defrosting CNS observed that the volume in the bag did not look like the 20ml that was stated on it. No leakage noted. CNS syringed contents out to confirm volume in bag, only managing to syringe out 11mls with a possible 0.5mls in the bag. All paperwork supported that a volume of 20ml should be in the bag, unable to verify the dose in the bag or establish where the discrepancy occurred the consultant decided not to infuse the cells.

8. **Liverpool - Reagents** - Adverse event initially raised relating to haemolysis problems in OR1r cells in Alsevers Lot R044 3241. The same type of haemolysis was also seen in other Reagents products (Panel 2 cells R141 3305, R142 3305, R152 3305, PTI Cells Lot 3859 and Allo Absorption Cells Lot R405 3369) as the preliminary investigation indicates the cause of this haemolysis is the same across the products.

9. **Liverpool - Supplier** - Tissue Banking - 4 bottles of TBIS were sent for Bacteriology lot testing and 1 bottle was found to be contaminated with Pseudomonas fluorescens. Batch was used for manufacturing prior to bacteriology results being received.

10. **Filton - BBMR**. 08/09/14 Incorrect BBMR donor details were sent to Anthony Nolan to work up for a Nottingham patient. Nottingham requested two different BBMR donors at CT stage. A preferred donor was identified out of the two. BBMR sent the incorrect donor details to Anthony Nolan. Anthony Nolan did not notice the error and proceeded to workup the donor. Error was identified during routine admin in BBMR when a release letter was sent to the donor who was inadvertently in workup. He contacted BBMR to say he was donating tomorrow.

April 2014 to June 2014

11. **Sheffield - CMT Stem Cells** Anthony Nolan donor was collected at Sheffield on 22/04/14. The CD34+ cell dose is calculated by a spreadsheet. On this occasion an incorrect recipient weight of 15.6Kg was entered into the spreadsheet. Procedures state that the spreadsheet is to be cross checked by a second member of staff, but due to excessive workload at the time, this check was not completed properly. The actual weight was 62Kg. This resulted in an adequate dose for transplant of 4.68 x 10^6/Kg being reported, when the correct dose was 1.17 x 10^6/Kg which was inadequate for transplant. As a result the donor was released, and the cells issued to the German courier. On the morning of the 23/04/14, the German transplant centre reported to the Anthony Nolan that the dose in the product was only 1 x 10^6/Kg. SCI checked the records and the error in the recipient weight was discovered. The incident was investigated and managed as a SUI and the recipient engrafted, despite the low dose, and is now doing well. I wider view of processes and spreadsheets where reliance is placed on manual entry and checks to ensure that there are no unknown risks similar to the one involved in this incident.

APPENDIX 6: CURRENT DOCUMENTS OVERDUE REVIEW

Quarter 4: 01/04/15

Owner Directorate	Document Count	Overdue review	% Overdue
BD	661	23	**3.4**
BTS	527	42	**9.8**
CLINICAL	660	14	**2.1**
Corporate Communications	4	0	**0.0**
Logistics	491	3	**0.6**
Emergency Planning Service	194	0	**0.0**
FIN	128	5	**3.9**
HR	166	2	**1.2**
ODT	513	41	**7.9**
PS	2,251	22	**0.9**
QA	371	3	**0.8**
DTS	5,108	75	**1.4**
Total	**11,074**	**230**	**2.0**

APPENDIX 7: BENCHMARKING DATA

SABRE REPORTS

Table 1: Calculated frequency of SABRE reports per 100,000 donations

	NHSBT	SNBTS	WBS	NIBTS
2012/13				
Quarter 1	1.9	22.9[1]	12.6[1]	0
Quarter 2	1.9	24.5[1]	0	0
Quarter 3	0.6	17.2[1]	0	0
Quarter 4	1.5	4.0	0	7[1]
2013/14				
Quarter 1	0.4	12.2	0	7[1]
Quarter 2	1.3	10.2	4	30[1]
Quarter 3	1.5	1.5	8	28[1]
Quarter 4	2.2	2.2	9	No Data Available
2014/15				
Quarter 1	1.8	8.0	0	0
Quarter 2	0.6	3.3	0	6.6
Quarter 3	2.8	3.4	4.0	19.8
Quarter 4	0.32	4.8	8.0	6.6

[1]relatively small numbers donated by comparison to NHSBT throughput mean that a small number of reports in a quarter have a big impact on the calculated frequency.

SAED REPORTS

Table 2: Calculated frequency of SAEDs reports per 100,000 donations

	NHSBT	SNBTS	WBS	NIBTS
2012/13				
Quarter 1	1.5	0	0	0
Quarter 2	1.1	0	0	0
Quarter 3	2.3	0	4.3[1]	0
Quarter 4	1.3	1	0	0
2013/14				
Quarter 1	3.3	0	0	0
Quarter 2	2.2	0	0	0
Quarter 3	2.0	0	0	0
Quarter 4	1.1	0	0	No Data Available
2014/15				
Quarter 1	2.0	0	4.5	0
Quarter 2	2.3	0	0	0
Quarter 3	2.8	0	0	0
Quarter 4	0.64	0	0	0

[1] 2010/2011 data

[2]relatively small numbers donated by comparison to NHSBT throughput mean that a small number of reports in a quarter have a big impact on the calculated frequency

Table 3: Breakdown of SAED findings April 2014 - March 2015

		WBS	NIBTS	NHSBT	SNBTS
1.	Death of donor within 7 days of donation regardless of cause	0	0	0	0
2.	Hospital admission of a donor within 24 hours of donation regardless of cause (admission means put into a hospital bed overnight and not just attended the ER)	0	0	25	0
3.	A donor sustains a fracture within 24 hours of donation	0	0	8	0
4.	A donor has a road traffic collision within 24 hours of donation	0	0	0	0
5.	A donor has problems relating to needle insertion persisting for more than 1 year	1	0	8	0
6.	A donor is diagnosed with Acute Coronary Syndrome within 24 hours of donation	0	0	1	0
7.	A donor suffers anaphylaxis, haemolysis or air embolism due to component donation	0	0	0	0

Table 4: Bacterial Screening Initial Reactive Rates (%)

	NHSBT	**SNBTS**	**WBS [1]**	**NIBTS**
2012/13				
Quarter 1	0.18	0.34	0.1	0.26
Quarter 2	0.18	0.10	0.1	0.38
Quarter 3	0.19	0.07	0.4	0.3
Quarter 4	0.14	0.20	0.1	0.91
2013/14				
Quarter 1	0.13	0.21	0.49	0*
Quarter 2	0.27	0.09	0.13	0.44
Quarter 3	0.21	0.07	0.04	0.56
Quarter 4	0.15	0.32#	0.91	No Data Available
2014/15				
Quarter 1	0.27	0.82	0.12	0.41
Quarter 2	0.11	1.01	0.17	0.69
Quarter 3	0.02	0.41	0.21	0.26
Quarter 4	0.11	0.45	0.27	0.2

*No bacteriology screening of platelets in May and June due to validation of industry bottles (only 75 platelets screened).

[1]relatively small numbers donated by comparison to NHSBT throughput mean that a small number of reports in a quarter have a big impact on the calculated frequency.

#SNBTS implemented anaerobic bacT/ALERT 24 February 2014

APPENDIX 8: REGULATORY HORIZON SCANNING

Legislation/Regulations/Guidelines	Regulator	Change	Date effective
ISO15189: 2012 standard, Medical Laboratories, Requirements for Quality and Competence	CPA to UKAS	CPA transition to ISO15189	Jan 2014
EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	MHRA	GMP Chapter 3 – Premises & Equipment	01/03/15
EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	MHRA	GMP Chapter 5 - Production	01/03/15
EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	MHRA	GMP Chapter 6 – Quality Control	01/10/14
EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	MHRA	GMP Chapter 8 – Complaints & Recall	01/03/15
EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	MHRA	GMP Annex 15 – Qualification and Validation	01/10/15
EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	MHRA	GMP Guidance note 14	published May 2014
FACT-JACIE	JACIE	Sixth Edition FACT-JACIE Standards	01/06/15
European Directive for the Quality of Medicines and Healthcare	Council of Europe	Guide to the preparation, use and quality assurance of blood components - 18th Edition	In consultation
European Blood Directives and EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	MHRA	Data Integrity	Phased - Complete by December 2017
European Tissue and Cells Directives	HTA	Import and Coding Directive	April 2017
European Blood Directives	MHRA	EU Blood Directives	Expected 2016-17