Significant changes from previous version: Introduction of release and exceptional release protocol. Annual BMT Laboratory report sent to BMT Director, BMT Consultant, Ward Sister and Transplant Coordinator

Purpose
This document represents the Quality Management Plan for the Blood and Marrow Transplant Laboratory (BMT), Royal Liverpool and Broadgreen University Hospitals NHS Trust.

It has been compiled to meet the requirements of JACIE Accreditation system and appropriate national and international standards.

The BMT Quality Management Plan must be read in conjunction with the Blood Science Quality Manual. The Blood Science Quality manual describes the Quality Management System of the Directorate of Blood Science at the Royal Liverpool and Broadgreen University Hospitals Trust (RLBUHT), of which BMT is a part.

1. General Information

1.1 Name and Address of Facility

| Name: Blood and Marrow Transplant Laboratory |
| Address: Haematology Department |
| 2nd Floor Duncan Building |
| Royal Liverpool University Hospital |
| Prescot Street |
| Liverpool |
| L7 8XP |
| Telephone: 0151 706 4348 |
| Fax: 0151 706 5810 |

1.2 Background

The number of conditions treated with haemopoietic stem cells has increased rapidly in recent years. In addition to bone marrow, alternative sources of haemopoietic progenitor cells (HPC) such as mobilized peripheral blood donations or cord blood are being used increasingly. The primary role of the laboratory is to provide high quality stem cell preparations and related products for the purpose of stem cell transplantation. The laboratory provides technical support for the José Carreras Transplant Unit at the Royal Liverpool and Broadgreen University Hospitals (RLBUH) and the Oncology Unit at Alder Hey Children’s
NHS Foundation Trust (AHCH). The purpose of this manual is to describe how the laboratory conforms to the standards and contents of the Human Tissue Act Code of Practice and the JACIE Accreditation Manual version 5.

1.3 Services
The Laboratory provides a service for all potential stem cell transplant patients referred to the Royal Liverpool and Broadgreen University Hospital and Alder Hey Children’s Hospital.
Dr. R Salim runs the RLBUH transplant program. Dr. M Caswell runs the AHCH transplant program.

Haemopoietic stem cells are routinely harvested from 3 sources:
- Bone Marrow
- Peripheral Blood in which stem cells have been mobilised using cytokines
- Cord Blood

In addition Donor Lymphocytes preparations are collected from peripheral blood.

On receipt by the laboratory the donations are processed in sterile conditions in Class II cabinets, located in a Hepa filtered cleanroom, into products appropriate for transplantation. The products may be infused immediately or cryopreserved for later use.

Haematopoietic Stem Cell Services available by the BMT laboratory include:
- Receipt and evaluation of HPC or lymphocyte preparations by the BMT laboratory.
- Dilution and pre-process storage of donations
- Paediatric and adult bone marrow collection. Guidance on collection and target volumes during collection procedures.
- Volume reduction of bone marrow donations using the Cobe Spectra equipment.
- Red cell depletion of ABO incompatible bone marrow donations.
- Accurate prediction of when to begin harvesting HPC, Apheresis collections.
- Quantification of CD34 positive stem cells and calculation of cell doses.
- Co-ordinate with NHS BT Liverpool and appropriate transplant ward to ensure adequate CD34+ cell doses from HPC-Apheresis collections.
- The use of tissue culture assay systems to demonstrate progenitor viability and process suitability.
- The preparation of donor lymphocyte infusions (DLI) in measured CD3 doses.
- The cryopreservation and long term storage of HPC and lymphocytes in the vapour phase of liquid nitrogen.
- Maintain all stored products under monitored conditions.
- The use of a trypan blue assay to assess the viability of all cellular therapy products.
• Monitor and document microbial contamination of HPC and therapeutic cell collections

• The organisation of safe and prompt transit of cellular therapy products between processing laboratory and hospital ward. Transport of HPC product and therapeutic cells in validated transport containers.

• Attendance at the thawing and reinfusion of cryopreserved products to ensure product quality, health and safety of nursing staff and suitability of infusion rates.

• Document all HPC and therapeutic cell collections. Records will be made with each step of the processing, testing, cryopreservation, storage and infusion or disposal of each product so that all steps can be accurately traced.

• Accurate record keeping on reagents/consumables used

• Identify and subsequently organise Volunteer Unrelated Donor Transplants using one of the British Bone Marrow Registries.

• The use of microbiological tests to assure the suitability of donors.

1.4 Guidelines and Standards

In order to ensure a high standard of processing in line with Good Manufacturing Practice (GMP) the laboratory practices have been implemented in line with the following guidelines:

• Clinical Pathology Accreditation (CPA)
• Human Tissue Act – Code of Practice
• JACIE Accreditation Manual 5th Edition
2. Personnel

2.1 Organisational Chart RLBUH

The laboratory provides a comprehensive range of services to support haemopoietic stem cell transplantation.
2.2 Organisational Chart AHCH

CONSULTANT PAEDIATRIC HAEMATOLOGIST / MEDICAL DIRECTOR Dr M Caswell

NHSBT CONSULTANT Dr T Callaghan

CONSULTANT PAEDIATRIC HAEMATOLOGIST Dr R Keenan and Dr H Campbell

APHERESIS

NHSBT Lead Nurse Specialist Therapies Sister S Jones

CLINICAL

BMT Co-Ordinator

LABORATORY

BMT Laboratory Manager / Facility Director N M Ginnity

Apheresis Staff Nurses

Semi-Permanent Deputy BMS S Hodgkinson

Support Staff BMS S Faulkner J Jones
2.3 BMT Quality Organisational Chart

2.4 Qualifications, Experience and Responsibilities of Key Personnel

N M'Ginness Stem Cell Laboratory Manager/ BMT Facility Director

- Chartered Scientist
- FIBMS
- 25 years experience working in 3 laboratories specialising in Haematology
- Stem Cell Laboratory Manager since 1997

See CV for further information.

Responsible for
- All procedures and administrative operations of the laboratory including compliance with the guidelines and standards outlined in section 1.4
• Liaise closely with the BMT Director, Transplant Consultant/Laboratory Medical Director, Transplant Co-Ordinator, Blood Science Directorate Manager and Quality Manager.
• Keep up to date with new developments, professional guidelines and related research.
• Ensuring that service level agreements or contracts for services with third parties are in place.
• Ensure procedures are followed.
• Approve and sign off procedures for process operations.
• Review product tests and procedures prior to product release.
• Validation.
• Training.

See Job description for further information.

Professor R E Clark BMT Director
BMT Director since 1990

See CV for further information.

Responsible for
• All medical aspects of the processing procedures.
• Keeping up to date with new developments, professional guidelines and related research.
• Development of clinical policies on donor suitability and care.
• Establishing and maintaining systems for clinical feedback.
• Authorisation of limited release in exceptional circumstances.

Dr R Salim BMT Consultant/ Laboratory Medical Director
Clinical consultant since 2009.

See CV for further information.

Responsible for
• All medical aspects of the processing procedures.
• Keeping up to date with new developments, professional guidelines and related research.
• Development of clinical policies on donor suitability and care.
• Establishing and maintaining systems for clinical feedback.
• Authorisation of limited release in exceptional circumstances.

Joyce Billington and Pamela Williams (Quality Assurance Manager).
The Quality Managers are the individuals who ensure, on behalf of laboratory management, that the quality management system functions correctly and efficiently.

• FIBMS
• Over 30 years experience specialising in Haematology
• Quality Managers since 2003

See CV for further information.

Responsible for
• Design and implementation of the Directorate Quality System
• Authority to introduce procedures and change quality procedures as deemed fit

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● Defined authority for reporting to Laboratory management on the functioning and effectiveness of the Quality Management System
● Acts as a Directorate audit officer and ensure the laboratory participates in audit programmes to ensure compliance with all appropriate regulatory requirements.
● Monitor the needs and requirements of the service users

**Dr J Anson Microbiological Advisor**
Contributing to the development of donor testing strategies

**Quality Control North West**
Develop and authorise strategies for environmental monitoring.
Development of strategies for the specification and monitoring of air conditioning and filtration equipment

The duties and responsibilities of all local posts are detailed in job descriptions and the post holders are appropriately qualified for their posts.

### 2.5 Bone Marrow Transplant Committees

#### 2.51 Bone Marrow Transplant MDT Committee
meets weekly

**Membership**
- Chairperson – BMT Consultant
- BMT Director
- BMT SPR
- Transplant Scientist
- Transplant Co Ordinator
- Transplant Ward Sister
- NHSBT Representative
- Principal Scientist H+I
- Data Manager

**Remit**
To plan and discuss all previous, current and forthcoming transplant patients.

#### 2.52 Bone Marrow Transplant MDT Quality Committee

**Membership**
- Chairperson – Directorate Manager Clinical Haematology
- BMT Director
- BMT Consultant/HTA Designated Individual
- Microbiology Advisor
- Transplant Co Ordinator
- Transplant Ward Sister
- Pharmacy Representative
- NHS BT Representative
- Laboratory Quality Representative
- Data Manager

**To maintain an efficient Blood and Marrow Transplant (BMT) Quality Management System. To ensure compliance with HTA, JACIE and CPA requirements. To implement quality objectives set by the BMT Quality Committee and the Blood Sciences Directorate Group. To discuss and action any quality issues.**
2.53 Audit, Quality and Clinical Governance meets monthly

Membership

Chairperson - Dr E Marks

Other members: Mrs J Billington
Mrs P Williams
Mr C Evans
Dr S Hawkins
Mrs S Levine/ Deputy
Mrs L Allars/ Mr I Andrews
Dr L Bailey/ Dr A Milan
Mr D Patterson/ Mr S Longman
Mrs B Street
Mrs S Hodgkinson/ Miss N M’Ginity
Mrs J Langdon
Mr D Tole
Mr R Jennings
Dr L Rowbottom
Dr K Lin
Dr D Barraclough
Ms M McGuinness
Ms J Ward
Clinical Scientist on rotational basis
SpR on rotational basis
Effectiveness Team representative
Any member of staff who wishes to discuss a “Quality” issue may attend on an “ad hoc” basis

To maintain an efficient Quality Management System. To ensure compliance with CPA, MHRA, JACIE and HTA requirements. To discuss and action any quality issues. To discuss the feasibility and likely benefits of carrying out specific clinical audits and to ensure a regular programme of audits is performed. Feedback from monthly Divisional Governance and Risk Group.

2.6 Training

The Department of Blood Sciences at the Royal Liverpool University Hospitals is committed to providing the highest level of training and development for all members of staff. Training and education shall be in accordance with the policies of the Trust. The training programme for staff includes:

- Corporate Induction
- Local Induction
- Mandatory Training (Fire Awareness, Health and Safety Awareness, Infection control, Information Governance, Manual handling)
- Quality Management System
- Laboratory Training

**New Staff Induction**

At the start of employment, all staff attends a Trust induction programme on a date as advised by the Development and Training Department. Training is given in mandatory Trust requirements for induction which include fire safety and manual handling.
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All staff then have a local Department induction, whenever possible on their first day in the Department, by the Directorate Manager or Deputy. An induction booklet is completed and kept in the staff file. Appropriate qualifications for all BMS and clinical scientists are again checked at appointment. If a Criminal Records Bureau check is required this is checked by the Human Resources Department. Staff are referred to the Trust Occupational Health Department where arrangements are made for the new staff member to receive any required vaccinations e.g. Hepatitis B virus.

- **Fire Awareness Programme**
  All new staff are given further basic fire awareness training by the local fire warden including the use of fire appliances and escape routes. Further reference to fire evacuation plans are also within the Department's Health and Safety Code of Practice. Additionally, when staff attend at the other Department sites, they are also instructed in evacuation routes etc.

- **Health and Safety Training**
  All staff are required to read the departments Health and Safety Code of Practice within the first few days of starting and then complete, where appropriate, a multi-choice questionnaire. When a member of staff has satisfactorily demonstrated a good health and safety awareness, a certificate is completed and filed in their training record file. Copies are also provided to staff for their records.

  Copies of the Health and Safety Code of Practice are available on the Document Management System, the Health and Safety notice board, Haematology Department 2nd Floor Duncan Building and the Quality Managers Office, CPA folder C.

- **Manual Handling**
  All new staff are instructed in manual handling techniques during the Trust induction week. Additionally, new staff are also made aware of manual handling issues as they are trained.

- **Basic Life Support**
  The Department has limited staff trained in basic life support. They are required to attend refresher training.

- **Quality Management System**
  All staff are instructed in the quality system of the department and kept up to date with quality issues by a range of methods.

  Quality is included in local staff induction and recorded in the induction booklet; there is also discussion of quality objectives at annual Personal Development Reviews, regular staff meetings where quality is an agenda item. Monthly quality bulletins are uploaded onto the electronic notice board and displayed throughout the department. Also minutes of audit, quality governance group meeting and the BMT Quality meetings are available on the electronic notice board. Representatives from all staff groups are part of the audit, quality governance group, including the Deputy BMT Biomedical Scientist. Quality refresher / update meetings are also held within the department on regular basis.

- **Department Computer Systems**
  All staff are given appropriate training in the use of the laboratory computer system organised by the IT Manager. Staff also have access to the Trust intranet and internet. For appropriate staff, training in the use of Hospital IT Systems e.g. the Patient Administrative System is provided by the Trust IT Department.
- **Ethics and Confidentiality of Information**  
  Training is given on induction by Trust personnel and regular update training sessions are available to staff. The Department also has a lead Caldicott trainer who ensures that Department update sessions are given when required.

- **Mandatory Training**  
  This programme is undertaken by the Trust's Training and Development Department and currently involves annual attendance for half a day. This is compulsory for all Trust staff groups.

- **BMT Training**

  **Title**  
  BMT Training Programme

  The BMT laboratory has a specific BMT training programme. All personnel trained in BMT procedures have a permanent training record kept in the BMT laboratory. At the beginning of each month a Quality and Training e-mail is sent by the BMT laboratory manager to all BMT staff. The e-mail is designed to inform staff of all Quality and Training issues. Topics discussed include NEQAS results, internal Quality Control results (e.g. environmental monitoring, positive microbiology cultures) and any training issues identified. Training records are reviewed yearly at the BMS Personal Development Review.

- **Personal Development Plans (PDP)**  
  At staff's annual appraisal, training needs, and where relevant, competency is reviewed. Also additional training needs to help individuals with their own professional and personal development plan may be identified and appropriate individual training needs / programme is planned.

- **Competency**
  
  - Competency will be assessed periodically for all HPC registered staff
  
  - Competency is re-assessed when appropriate for all staff following an internal error or incident, prolonged absence from work or audit findings suggest a problem. All appropriate records are kept.
  
  - If when competency is assessed the individual fails, the competency will be re-assessed. If failed again the individual will be reviewed in line with the Trust Capability Policy. HPC registered staff will also be reviewed in line with HPC standards.
  
  - If an individual repeatedly fails to submit competency assessments when due the individual will be reviewed inline with the Trust Capability Policy and Trust Disciplinary Policy. HPC registered staff will also be reviewed inline with HPC standards.
  
  - Various assessments are in place in the BMT laboratory to ensure all staff are competent to perform their work. See SOP Competency Assessments in the BMT Laboratory
3. Premises and Equipment

3.1 The Hospital
The Royal Liverpool University Hospital opened in 1978 and replaced several small city hospitals some of which had been established for over 150 years. The hospital is located near the city centre and has the main Accident and Emergency Department. It is a major teaching hospital in the Mersey region for the University of Liverpool and is adjacent to the University Campus. It became a self governing trust within the NHS in April 1991 and subsequently amalgamated with Broadgreen University Hospital NHS trust to form the Royal Liverpool and Broadgreen University Hospitals NHS Trust in 1995 (RLBUH).

In total the RLBUH has over 49 wards and specialist clinical areas providing 963 beds for inpatient care. During the week up to sixteen outpatient clinics operate at any one time providing services for over 300,000 outpatients per year. The major acute services are based within the Royal, together with regional and national specialist services in nephrology, Renal Transplant, Renal Dialysis, Ophthalmology, Haematology, Blood and Marrow Transplant and Vascular Surgery.

The Liverpool Heart and Chest Hospital provides cardiothoracic surgery in Broadgreen Hospital.

Obstetrics and gynaecology services are provided by the Liverpool Women’s Hospital.

3.2 The Laboratory
The BMT Laboratory consists of 2 areas known as:

1. The BMT Laboratory (Room 2028).
2. The Cleanroom (Room 2030).

A plan of the 2 areas is shown below:
Blood and Marrow Transplant Clean room

FLOW CABINET 2

FLOW CABINET 1

STOOL

SHELF
3.21 The BMT Laboratory

**SOP Title**
BMT Facility Management

The laboratory is separated in to 4 areas:

1. The long term liquid nitrogen storage area and cryogenic freezing takes place on one side of the laboratory. Currently the Laboratory has 5 storage tanks. Liquid nitrogen is piped into the laboratory from a cylinder outside the Duncan building into an inlet in the wall. The laboratory is fitted with an Oxygen Depletion monitor and extractor fan as a health and safety measure. All storage vessels are monitored by temperature probes linked to a central control area in addition to the storage tanks own internal monitors. All temperature deviations out of range sound an alarm that is monitored and recorded at all times. Procedures for responding to alarms are contained in standard operating procedures.

2. The centre bench is designated for laboratory analysis of peripheral blood samples or aliquots from therapeutic cell collections. Analysis includes CD34 and CD3 measurements, colony incubation and analysis and cell viabilities.

3. The final bench is used for product receipt and gathering and recording consumables/reagents for cell processing in the cleanroom.

All documentation pertinent to the BMT laboratory is stored on designated book shelves; this includes current and past patient worksheets. Patient records are separated in to HPC, Apheresis, HPC, Marrow, HPC, Cord Blood and TC-T collections. Records are further stored alphabetically and in date order.

4. Finally there is a separate designated BMT office area which includes PC, printer and telephone access.

3.22 The Clean Room

**SOP Title**
Working in the Cleanroom
Cleanroom Maintenance
Environmental Monitoring in the Cleanroom
Environmental Monitoring Results

This area consists of 2 rooms built to GMP standards. Controlled access from the corridor leads to the change room which is linked to the cleanroom.

All rooms receive HepA filtered air at 19°C-23°C and are designed to comply with relevant guidelines. The clean room has an air quality of grade B classification and the change room has a grade C air quality. Laminar airflow cabinets in the cleanroom provide grade A air quality for open processing operations.

The clean room is set up to achieve 10 Pascal's differential pressure from the clean room to the change room and 10 Pascal's differential pressure from the change room to the corridor. This works on a cascade effect to prevent dirty air being drawn into the clean room when the doors are open. The overall differential pressure from the change room to the corridor being 20 Pascal's differential pressure.

A magnehelic gauge is fitted inside the change room to measure the differential pressure between the clean room and the change room. This is recorded daily by BMT laboratory staff and as part of the Estates Department maintenance schedule. Records are available in the BMT Laboratory. A magnehelic gauge is also fitted in the corridor outside the change room to measure the differential pressure.
between the change room and the corridor. This is recorded daily by BMT laboratory staff and as part of the Estates Department maintenance schedule.

The clean room is supplied with a minimum of 20 changes of air per hour.

The maintenance of the clean room is provided by the Estates department, a manual is available for inspection. The clean room facility was validated on completion by the suppliers and also by the BMT Laboratory in conjunction with Quality Control North West.

The construction of the clean room has been designed to minimize particle build up with a vinyl finish to all surfaces and fittings near to flush with walls.

BMT Laboratory staff are responsible for cleaning the cleanroom. Cleaning occurs weekly before environmental monitoring and after each cellular processing. The cleanroom is also given a deep clean every month which includes the walls and ceilings. The Clean room is monitored for particles, bacteria and fungal contaminations both weekly and during each process. The methods for cleaning and environmental monitoring are documented within SOP’s.

The change room is used for the gowning procedure and preparation of consumables in to the clean room. Entry of personnel and items into the clean room is restricted and described in standard operating procedures.

### 3.3 Maintenance and Servicing

#### 3.3.1 General

Maintenance is divided into two types:

1) Planned maintenance, where regular inspections and servicing are undertaken
2) Day-to-day maintenance, where faults and breakdowns are reported directly to the BMT Laboratory manager or a contractor.

A log is used to record service and maintenance history for all equipment that affects product quality. Service and maintenance contracts for critical equipment are supplied by the manufacturers or approved suppliers.

Service reports and/or calibration records for laboratory equipment are held in the BMT Laboratory in a file labelled Service/Maintenance Reports.

As part of the equipment management process the next service due dates are recorded in a spreadsheet entitled BMT Equipment Service Record located in the Maintenance and Alarm check folder in the BMT folder on the Haematology Hard drive. The spreadsheet records how many services are required per year.

The service due dates are also recorded in the laboratory diary at the beginning of the month that the service is due.

All equipment is labelled with the last service date and date the next service is due.

In addition to scheduled maintenance, the haematology analyser and flow cytometer are calibrated and checked using controls at defined intervals by laboratory staff using appropriate methods and the information is recorded. Maintenance contracts include call-out to deal with any unexpected problems that are identified by these checks.
3.32 Cleanroom Servicing
The cleanroom is serviced by the Estates department. On completion of the service a Cleanroom Monthly, Six monthly or annual logs are sent to the BMT Laboratory Manager. A record is kept in a folder in the BMT laboratory Room 2028.

HepA filter integrity is carried out by NWQC on an annual basis. Any problems are dealt with by Estates or by a subcontractor employed by Estates.

Equipment such as Laminar airflow cabinets situated in the clean room are serviced in situ. The cleanroom and Laminar flow cabinets are cleaned immediately after a service visit.

3.4. Cleaning and disinfection procedures

SOP Title
Working in the clean room
Clean room Maintenance
Cleaning Procedures for Laboratory Equipment and Non clean room areas

Cleaning and decontamination procedures are essential to achieve and maintain an operational level of cleanliness appropriate to the activities of a laboratory preparing cellular products for clinical use.

3.41 Clean room
Bactericidal/fungicidal disinfectants (Biocides) are used on a rotational basis along with 70/30 alcohol to achieve and maintain microbial contamination below the recommended limits. Disinfectants and alcohol are selected for their mode of action and for their efficacy when used in combination. When dealing with potential blood spillages cleaning requires a water based detergent such as Biocide A and B for worktops and surfaces and Proceine and Qceine for the floor. Lint free sterile cloths are used in the grade A and B areas. The inside of the Laminar air flow cabinet and any equipment that is in direct contact with products is cleaned before and after each procedure using sterile alcohol spray and sterile Biocide A/B if necessary. The inside of the cabinet, all the worktops and floor area in the clean room and change room are cleaned post sessional and pre environmental monitoring.

Once a month it is necessary to clean the entire clean room and change room including contents. This includes the ceilings, walls, floors, doors including handles, viewing panel, worktops including base and legs, shelf, step over stool and all equipment such as cabinets (external), heat sealer, blood strippers, particle counter, chairs, bins, plastic tray, storage containers, step ladder, mop and clean room shoes.

Records are kept of all cleaning. Extra cleaning is performed if environmental monitoring suggests this is necessary.

All materials and consumables are sprayed with 70% Ethanol with Hydrogen Peroxide and wiped with 70%IPA wipes before introduction in to the clean room. The consumables are sprayed further with 70% sterile IPA and wiped with lint free sterile cloths before introduction to the class II cabinets. This method is validated annually by Quality Control North West.

3.42 BMT Laboratory
Floors are cleaned by the laboratory cleaner daily. All benches and equipment are cleaned regularly using Virusolve+. All cleaning is done to schedules and recorded. Spillages of blood or similar products are cleaned immediately.

Equipment that has been in contact with cellular therapy products that have virology marker positive results is decontaminated immediately.
4. Health and Safety
The Blood Science Department has a Health and Safety code of practice to ensure a safe environment within the laboratory for staff and visitors. The Directorate Management fully undertakes its responsibilities to ensure a safe environment in the laboratory for staff, visitors and patients.

All staff are informed of the Directorate’s Health and Safety Code of Practice upon Induction.

All staff are aware of their individual responsibilities regarding health and safety. There is a comprehensive set of safety policies and procedures.

There is a designated Health and Safety Manager, Deputy and Health and Safety Group who are responsible for day-to-day management of health and safety issues.

The health and safety procedures cover:

- Action in the event of fire.
- Action in the event of major spillage of dangerous chemicals or clinical material.
- Action in the event of inoculation incident.
- Recording and monitoring of accidents and incidents.
- COSHH/risk assessments.
- Disinfection processes.
- Decontamination of equipment.
- Chemical Handling.
- Storage and disposal of waste.
- Specimen collection and handling, transportation, reception and referral to other laboratories.

Safety notices for the benefit of all staff and visitors to the Department are displayed. Work areas are kept clean and uncluttered.

Policies and Procedures are in place within the Trust and Blood Science Department, supporting the Health and Safety Policy to minimise the risk to the health and safety of employees, patients and visitors to the laboratory.

4.1 Trust Policies

SOP Title
Health and Safety Policy
Control of Substances Hazardous to Health
Induction and Mandatory Training Policy
Risk Assessment Policy
Risk Management Strategy
Manual Handling Policy
Smoke free Policy
Fire Safety Policy
Personal Protective Equipment Policy
Bomb Incident Plan
New and Expectant mothers Policy
Management of Contractors working on and within Trust Premises
Medical Devices Management and Decontamination Policy and Procedure

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4.2 Blood Science Policies  

SOP Title  
Health and Safety Code of Practice  
- Risk Assessments  
- Visual Display Units  
- Fire Regulations  
- Handling of Electrical equipment and other machinery  
- Health and Safety inspections  
- Disinfectant Policy  
- Decontamination of equipment Procedure/Permit to work  
A guide to Health and Safety in a Clinical Laboratory Setting  
Health and Safety Guide – Clinical Laboratory Medicine  
Staff Training and Education  
- Fire awareness  
- Health and Safety  
- Manual Handling  
- Quality Management System  
Induction Booklet  
Transportation of Pathological Samples  
Model Rule for Visitors  
Rules for Taxi Drivers  
Procurement and Management of Equipment  
Incident Reporting Policy and Procedure  
Control of Process and Quality Records  
Control of Clinical Material  
Major Incident Procedure  
Procurement and Management of Equipment  
Staff Working Hours  
Risk Management Strategy  

All Trust policies are available on the intranet. All Blood Science Department Policies are available on the Document Management System. In the case of a computer breakdown a copy of the Health and Safety Code of practice is available in the Quality Managers office (CPA folder C) and the Health and Safety notice board.

4.3 BMT Laboratory Policies  

4.31 Liquid Nitrogen Handling  
SOP Title  
Safety Precautions for Liquid Nitrogen  
Liquid Nitrogen Handling in BMT laboratory  
Procedure to follow if the Oxygen Depletion Monitor Alarms  

All staff in the BMT laboratory are trained in the safe use and storage of liquid nitrogen. Personal Protective Equipment is available, including thermal gloves and full face visor.

An Oxygen Depletion Monitor and Extractor Fan are installed in the BMT laboratory. The normal level of oxygen in the air is 21%. When the oxygen level falls below 19% the alarm is activated. A solenoid valve shuts preventing any more nitrogen entering the laboratory: a fan blows fresh air into the laboratory whilst an extractor sucks the nitrogen out of the laboratory.

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4.32 Environmental Monitoring

SOP Title
Environmental monitoring in the Cleanroom.
Environmental monitoring results
Personal protective equipment in the Cleanroom

This includes:
- Weekly particle counting of the change room, cleanroom and Class II cabinets in operation and rest. The results are assessed by the BMT Laboratory Manager.
- Quality Control North West provides quarterly environmental monitoring of the cabinets, change room and cleanroom using particle counts, air monitoring and contact plates.
- Sessional monitoring of the cabinets using settle plates, contact plates and finger dabs. The plates are assessed by Quality Control North West.
- Weekly monitoring of the cabinets (in rest), change room and cleanroom using settle plates and contact plates. The plates are assessed by Quality Control North West.
- Clean room garments are used at all times in the cleanroom. These include a sterile polyester gown, sterile gloves, overshoes and theatre caps.
- There is a ‘Sticky mat’ in the entrance to the cleanroom.
- There is controlled access to the cleanroom.
- Sterile mops impregnated with Proceine or Qceine are used daily to clean the cleanroom floor and monthly to clean the clean room walls and ceiling.

4.33 Monitoring microbial contamination of harvested products

SOP Title
Monitoring microbial contamination of all harvested products.

All measures must be taken to avoid contaminating the harvest with bacteria. Samples for Medical Microbiology are taken post harvest and post processing from all harvests.

Once a month the microbiology results are reviewed by the Laboratory Manager. A report is made using the Haematology Internal Quality Control review form. Reports are kept in the BMT Quality folder.

Yearly an audit is carried out on positive cultures from harvested and processed material. Findings from all audits are discussed at the Audit, Quality and Clinical Governance group and BMT Quality meetings. Minutes from all meetings are available on the Document Management system.

4.34 Virology Screening

SOP Title
Pre BMT procedure requirements.
Release and Exceptional Release of Cellular Products to the Ward

A virology screen including Hepatitis B (Hep BsAg and Hep B core), Hepatitis C and HIV is taken on all patients/donors before harvesting and the results known to be negative before placing any material into the liquid nitrogen storage vessels.
A quarantine tank is available to store harvests from patients with virology results pending. On notification of a negative virology screen the material can be transferred into the appropriate long-term storage vessel.

All material harvested from donors must be known to be HIV, Hepatitis B (Hep BsAg and Hep B core), Hepatitis C and Syphilis negative before being reinfused into the recipient. In the exceptional circumstance
of cellular therapy products being used from a donor with a positive virology the BMT Consultant must authorise the urgent medical need and approve of its issue.

4.35 High-risk Harvests
SOP Title
High-Risk Therapeutic Cell Collections

High-risk material must be stored separately. A high-risk tank is available to store all known high-risk material.

4.4 Health Requirements
All staff are appointed subject to health clearance by Occupational Health. Managers are responsible for monitoring and referral of employees to Occupational Health in accordance with Trust policies.

4.5 Personnel Hygiene Requirements Including Clothing
SOP Title
Personal Protective Equipment in the Cleanroom

The Bone Marrow Transplant Laboratory has established standards that state the requirements for cleanliness, hygiene and environmental control in the areas where human cells for cellular therapy are processed.

Hand wash facilities are provided in all laboratories. The Blood Science Department is equipped with adequate washing facilities for male and female staff. A staff tea room is available equipped with tea making facilities and a microwave oven. In addition, there is a large dining area and coffee shop on site.

All laboratory staff are required to wear protective polyester/cotton laboratory coats whilst working in laboratory areas. Laboratory coats are changed weekly or sooner if soiled.

Clean room garments are required for entry into the BMT clean room. The garments are designed for the application and are obtained from Micron Clean. The garments are worn for a maximum of one session, after which, they are hot washed in detergent/biocide, dried in a stream of filtered air and irradiated before re-use.

5. Quality Management

5.1 Blood Science Quality Manual and Quality Policy

Includes:

- A description of the laboratory’s organisational structure including the laboratory’s place within the organisation and lines of communication to Trust Board level.

- A copy of the laboratory Quality Policy.

- A description of the documentation (policies, procedures etc) used in the Blood Science Department.

The document is controlled and regularly reviewed.

The main elements of the quality system are specified in a series of documented policies, standards and, where necessary, specific instruction in the operation of the system provided through Standard Operating Procedures (SOPs). These elements include:

- Management Quality Reviews
- Quality incidents and complaints
- Corrective and preventative action, including recalls and concessions
- Quality audit
- Document control
- Maintenance and calibration
- Cleaning and hygiene
- Validation

SOPs produced by the Quality Department are listed below:

**SOP Title**
Validation in Haematology
Management of Change Control in Haematology
Error logging
Departmental Complaints Procedure
Internal Quality Audit SOP for auditors and auditees
Procurement and Management of Equipment
Health and Safety Code of Practice
Identification and Control of Non compliances
Document Management System Users Guide
Assuring the Quality of Examinations in Haematology
External Quality Assessment in Haematology
Assessment of User Satisfaction
Quality Improvement Procedure

SOP’s produced by the BMT Laboratory are listed below:

**SOP Title**
Booking and Receipt of Human Cells for Therapeutic Use
Review Procedure for all BMT harvests
NEQAS CD34 Stem Cell Enumeration Scheme
Investigation of Errors, Accidents and Adverse Events in the BMT Laboratory
Product Labelling
BMT Equipment Management
Competency Assessments in the BMT Laboratory
Release and Exceptional Release of cellular products to the Ward
Maintenance of the Class II Laminar Flow Cabinets
Cleaning Procedure for Laboratory Equipment and non cleanroom areas
Validation of Equipment, Processes and Reagents in the BMT Laboratory
Internal Quality Control in the BMT Laboratory

5.2 Responsibilities of the Quality Management System.
The purpose of the Quality Management System is to help all staff improve what they do for the benefit of patients. This involves:

- encouraging common ownership of quality
• educating all staff in quality principles
• promoting a philosophy of continuous improvement
• providing expert advice and practical assistance in the application of systems of quality assurance in compliance with standards
• help to identify quality indicators and monitor performance
• help to define best practice by the use of facts and measurable parameters
• direct intervention in processes if quality and patient safety are placed at risk

Within the quality systems the Quality Department retains direct responsibility for the following activities:
• the development and management of the internal quality audit
• the development and management of the complaints system
• the development and management of the system for quality incidents and ensuring corrective and preventative action is taken in response to incidents
• the development and management of the document and data control system
• ensuring the validity of quality management information including component quality monitoring data

References
Induction Booklet
Quality Improvement Procedure
Quality Monthly Bulletin

6. Policies and Procedures

6.1 BMT Policies
Policy for Discarding Previously Harvested Material
Contingency Agreement with Central Manchester University Hospital
BMT Training Programme

6.2 BMT Laboratory Standard Operating Procedures
Critical procedures are detailed in documented SOPs that are controlled by the Quality Assurance Department and are subject to validation and regular review. SOP’s are kept in the BMT Laboratory.

6.21 Introduction to the Laboratory
SOP Title
BMT Facility Management
BMT Staff Guide
Stem Cell Laboratory Services
BMT SOP for SOP’s
Expected End Points for Procedures in the BMT Laboratory

6.22 Emergency and Safety Procedures
SOP Title
BMT Emergency Plan
Safety Precautions for Liquid Nitrogen
Liquid Nitrogen Handling in the BMT Laboratory
Provision of Liquid Nitrogen to Other Users
Procedure to be followed if the Oxygen Depletion Monitor Alarms
Procedure to be followed if one of the Storage Tank Alarms
Procedure to be followed if the Electricity supply to the Storage Tanks Fail
Catastrophic Failure of a Storage Tank

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6.23 Clean room
SOP Title
Working in the Cleanroom
Cleanroom Maintenance
Personal Protective Equipment in the Cleanroom
Environmental monitoring in the Cleanroom
Environmental Monitoring Results

6.24 Maintenance
SOP Title
BMT Equipment Management
Maintenance of the Class II Laminar Flow Cabinets
Cleaning Procedure for Laboratory Equipment and Non Cleanroom areas
Cleaning the Liquid Nitrogen Storage Tanks
BMT Maintenance and Alarm check Forms

6.25 Protocols
SOP Title
Booking and Receipt of Human Cells for Therapeutic use
Pre BMT Procedure Requirements
Donor Selection Criteria
Management of Allogeneic Stem Cell Transplants
Protocol for Harvesting HPC, Apheresis collections
Product Labelling,
Transportation of Non-Cryopreserved or Cryopreserved collections
Conditions for the Storage and Disposal of Harvested Material
Review procedure for all BMT harvests
Release and Exceptional Release of Cellular Products to the Ward
Recall Procedure
Monitoring microbial contamination of harvested products
Internal Quality Control in the BMT Laboratory
Investigation of Errors, Accidents and Adverse Events in the BMT laboratory
Validation of Equipment, Processes and Reagents in the BMT laboratory
Competency Assessments in the BMT Laboratory

6.26 Record Keeping
SOP Title
BMT Record Management System
Use of Telepath Computer System and numbering system for BMT Results
Kryotrak Storage System
Contronics Alarmsg
Stores Database
BMT Worksheets
Reagent Monitoring and Record Keeping
Monitoring Engraftment Data
Telephoning and Faxing Results in the BMT Laboratory
Transfer of BMT Samples to Other Sites
6.27 Irradiator
SOP Title
Calculation of Time required for the Irradiation of Blood and Platelets
Measurement of radiation dose around the blood irradiator
Dose Mapping validation
Overview of Calibration in Transfusion Practice

6.28 Laboratory Procedures
SOP Title
Harvesting of Bone Marrow in Theatre
Manual Mononuclear Cell Separation using the Cobe Spectra
Plasma Depletion of Allogeneic Transplants
Red Cell Depletion using Hydroxyethyl Starch.
Freezing Collections in a 10% solution of DMSO
Freezing Small Aliquots of Cells in a 10% solution of DMSO
Use of the Kryo 560-16 Programmable Freezer
High risk Therapeutic Cell Collections
CD34 Stem Cell Enumeration by Single Platform using the FACSCANTO™II
Use of the FacsCalibur for CD34 Analysis
CFU-GM Assays
Determination of Cell Viability using Trypan Blue
CD3 estimation using the FACSCANTO™II
T-cell Depletion using Campath-1H
Donor lymphocyte Infusion
ABO and Rh Testing of Components Prior to Transplantation
Thawing Cells for Therapeutic Use on the Ward
Thawing of Cryopreserved Cord Blood for Transplantation
Use of the Dry ShipsLog Temperature Alarm Data Logger
Problem samples in the BMT laboratory
Directed Cord Blood Collection, Testing and Cryopreservation
NEQAS CD34 Stem Cell Enumeration Scheme

All new and revised SOP’s are read by the relevant staff. Their training records and DMS system record that the document has been read and understood and training has been completed, prior to implementation.

7. Document Control

SOP Title
Document Management System – User Guide

Copies of all the procedures required for the laboratory to operate are kept in the BMT Laboratory. Procedures for the preparation, implementing and review of all documented procedures are set out by the document control section of the Quality Department.

The document describes the procedure for the control of all documents (internally generated and from external sources) throughout the Directorate of Blood Sciences on all 3 sites (Royal Liverpool University Hospital, Broadgreen Hospital and Liverpool Women’s Hospital). An in-house database is utilised, commonly known as “The Document Management System” or DMS.
7.1 Overview of Document Management System
This system serves to ensure that:
- Documents are approved by authorised personnel prior to use
- Documents are uniquely identified
- There is an up to date master index identifying current versions
- Documents are reviewed at appropriate intervals
- There is an audit trail of document history
- There is a record of procedures that have been superceded or made obsolete
- Active, authorised documents are available to all staff at all times

7.2 System Structure
The version number of the DMS changes when the database is upgraded. The database is located on the departmental z: drive and is password controlled.

Only authorised managers will be given access to the system.

This system facilitates the introduction of new documents and their posting to a DMS Web version with relevant details.

The Web version, which is built from the DMS database, will be available to all staff and will allow access to all authorised active documents. Users can access the DMS via the electronic notice board. To ensure that staff are made aware of new and modified documents, the front page of the web version will display a list of all documents that have been introduced or modified within the last 30 days. The web page is updated and completely rebuilt each day. Any document that is not available through this route has no status in the department.

7.3 Document Identity
When documents are introduced to the system the following information must be supplied before the system will allow the document status to be set to ‘Active’.

a) Title
b) Version number
c) Name of document manager
d) Name of author
e) Name of authoriser

In addition the document must be coded. The coding system has five elements:

Department (2 letters) e.g. BS (for Blood Sciences)
Section (subcoding) – use drop down menu
Document Type (1 letter)
- A = Audit
- F = Form
- C = COSHH Assessment
- I = Information
- P = Policy
- R = Risk Assessment
- S = Standard Operating Procedure

Site (1 letter)
7.4 Responsibility
The IT Manager and system administrators are responsible for the maintenance of this system on a regular basis. The Quality Managers send a monthly review report to all document managers and a copy is sent to the Clinical Director. Document managers should ensure that all documents are reviewed in a timely manner. Documents past review date are discussed at the Audit, Quality & Governance Group and Performance Review Group monthly meetings. Both meetings are attended by the Director Manager and Clinical Director.

7.5 DMS Training

SOP Title
How to access and use the Document Management System (DMS)

Users and document managers receive in house training. DMS training sheet records are held by the Quality Managers.

8. Audits and Validations

8.1 Audits

SOP Title
Internal audit is described in procedure [Internal Quality Audits – Standard Operating Procedure for Auditors and Auditees].

Audit – systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Audits are conducted to ensure that the Quality management plan is operating effectively, as well as that technical procedures are being performed appropriately and to identify trends and recurring problems.

Internal Audit of Quality Management System
The Quality Management System of the Directorate is subject to planned and scheduled internal audit against agreed criteria. The responsibility for management of audits is with the Quality Managers, the inspections are carried out by staff trained in auditing.
The record of this process includes the activities, areas or items audited, any non-conformities or deficiencies found, and also recommendations and time scale for corrective and preventative actions.

The records of internal audit are regularly evaluated and decisions taken, documented, reviewed and acted upon.

**Internal Audit of Examination Processes**

There is an internal audit of the pre-examination, examination and post-examination processes in the Blood Science Department. The process of internal audit is planned and scheduled and is conducted against agreed criteria carried out by trained personnel. The audits are arranged by Blood Science Quality Managers. A copy of the audit schedule can be found on the DMS and on the Quality notice board. The record of this process includes the activities, areas or items audited, any non-conformities or deficiencies found, and also recommendations and time scale for corrective actions. The records of internal audit are regularly evaluated and decisions taken documented, monitored and communicated.

Additional audits are arranged by the BMT Laboratory Manager specifically for the BMT laboratory to include those for which a lack of compliance would potentially result in an adverse event. A copy of the schedules can be found on DMS, on the Quality notice board and in the Audit file in the BMT laboratory.

Reports from all BMT audits are presented at the Blood Science Audit, Quality and Clinical Governance meeting and BMT Quality meeting. Any action points are documented in the minutes and reviewed appropriately. Copies of reports can be found in the Audit file in the BMT laboratory.

The BMT Laboratory Manager/Facility Director is responsible for ensuring that BMT audits are performed as scheduled and that corrective and preventative action is completed. The Quality Manager is responsible for ensuring that follow up audits are carried out to verify that corrective actions have been completed and are effective in rectifying non compliances.

In addition the BMT Laboratory is audited for compliance with the Human Tissue Authority, Clinical Pathology Accreditation and FACT-JACIE International Standards for Cellular Therapy Product Collection Processing and Administration Accreditation Manual.

**8.2 Validations**

**SOP Title**

Validation of Equipment, Processes and Reagents in the BMT laboratory

Validation is confirmation by examination and provision of objective evidence that specific requirements can be consistently fulfilled. Process validation is required to ensure that procedures, processes, equipment, materials and systems produce the desired results.

The adoption of a structured validation strategy leads to:

- Delivery of quality results, fit for purpose, delivered on time and which meet the expectation of users.
- Cost effective implementation of facilities, equipment systems and processes.
- The delivery of facilities, equipment systems and processes which are well defined, documented and easy to use, supported and maintained through an obligation to address user training and produce supporting SOP’s.

Processes are validated as follows: -

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- Specify objective and measurable criteria for assessment.
- Create a validation plan.
- Identify the duration of the validation process.
- Select the methods and tools for validation.
- Statistical methods for assessment of validation where appropriate.
- Perform installation, operational and performance qualification when necessary and document results.
- Determine continuous process controls.

In the BMT laboratory validation is needed for changes to:
- Starting material e.g. reagents, consumables
- Procedure/Method
- Environment
- Equipment

Critical Procedures must be revalidated regularly. These include:

1. Processing
2. Cryopreservation
3. Labelling
4. Storage
5. Distribution

Any revalidation should be documented.

A list of revalidation studies is prepared by the BMT laboratory manager. A copy of forthcoming studies can be found in the validation file. All significant procedures, processes, equipment, reagents and containers are continually monitored throughout the year with validation studies.

At the beginning of the month the objective, plan and acceptable results of the current study is drawn up by the BMT laboratory manager. Laboratory validations must be performed by appropriately trained staff.

A report is made using the Validation study in the BMT Laboratory form, by the BMS(s) conducting the validation study. Part of the report examines any problems encountered with the equipment e.g. breakages or any maintenance issues since it has last been validated.

The report is reviewed by the BMT laboratory manager and any resulting follow up action documented. The report must be signed and dated on completion.

The report must be reviewed by a member of the Quality Committee and signed and dated on review. If changes are implemented as a result of the study the report should be discussed at the next BMT quality meeting.

A copy of all validation reports can be found in the validation file.

Reagents purchased are validated by the Certificate of analysis. All certificates of analysis for supplies/reagents received into the laboratory are signed and dated on receipt. The certificates are scanned onto the Haematology hard drive into a folder named BMT Reagents.
9. Outcome Analysis

SOP Title
Monitoring Engraftment Data

Patients that have undergone stem cell transplantation, remain pancytopenic for some time until Haematopoietic Progenitor Cell (HPC) engraftment. These patients may require supportive therapy including infusion of platelets, red cells and growth factors. Low numbers of circulating myeloid cells, especially neutrophils are associated with a high risk of bacterial infection. Administration of G-CSF may accelerate neutrophil recovery decreasing the risk of infection during the early post transplantation period.

Granulocyte and platelet recovery are the earliest milestone in the short term success of haematopoietic recovery from allogeneic or autologous transplantation. Engraftment of erythroid and immune cells takes longer (weeks to months).

The day of infusion of HPC is designated as transplant day 0. This is the time from which recovery is measured. Post transplant engraftment is defined by a sustained neutrophil count >0.5x10^9/L. The day of myeloid engraftment is the first day of 3 consecutive days with a neutrophil count greater than 0.5x10^9/L.

Engraftment typically occurs 20-25 days after bone marrow infusion and 15-20 days after peripheral blood stem cell transplant. Adequate erythroid and megakaryocytic engraftment usually follows but in some instances, more commonly in VUD (Volunteer Unrelated Donors) patients, platelet and red blood cell support may be required for a prolonged period post transplant. The day of platelet recovery is defined as the first day of an unsupported platelet count >20x10^9/L (i.e. sustained without transfusion for 7 days).

Graft failure may occur in 1% of sibling allogeneic stem cell transplants, 5-10% of unrelated donor transplants and up to 20% of cord blood or haplo identical transplants. It is a rare occurrence after autologous stem cell transplant.

Timely engraftment of the recipient is directly related to the quality of the progenitor cell product. Documentation and review of time to engraftment after haematopoietic progenitor cell infusion is part of the BMT Quality Management Plan.

The engraftment data is recorded on a database stored on Haematology hard drive in a folder named BMT. There is a separate table for RLBUH patients and AHCH patients. The engraftment data for RLBUH patients are also entered on the Master BMT database. The master BMT database has information from all patients that have had a stem cell transplant at the Royal Liverpool University Hospital. The database is regularly updated by the Data Manager, the BMT Laboratory Manager and the BMT Director.

All engraftment times are reviewed at the BMT Quality meeting. Patients with delayed engraftment/graft failure will need further investigation. This may be resolved in the meeting by discussion with the Professor Clark/Dr Salim or by examining the patients processing records. A record is kept in the minutes.

A Quality and Training e-mail is sent monthly to all BMT staff informing them of any engraftment issues.

Yearly engraftment data is analysed to monitor trends. The analysis is split in to adult and paediatric patients.

The analysis consists of
The number of transplants reviewed
Category of transplant e.g. Allo HPC, A, Allo HPC,M, Allo HPC,CB, Auto HPC,A, Auto HPC,M
Number of cases per category

Anomalies

Where there is sufficient data for each category of transplant e.g. Auto HPC-A, Allo HPC-A etc the data is presented graphically and includes the mean days to white cell, neutrophil and platelet engraftment. Cases of late neutrophil engraftment are referred to specifically for discussion and follow up if necessary.

White cell, neutrophil and platelet engraftment is also compared graphically to CD34 cell dose administered. The median engraftment data for each category of transplant is compared to the previous years and presented in a tabular format. This should be able to detect drift in engraftment outcome. Finally in summary slide presents the frequency of cases of late engraftment for each transplant category.

Usually the paediatric review only involves a few patients. The paediatric data are presented in table format highlighting any cases of delayed engraftment.

Engraftment analysis is presented at the Blood Science Audit, Quality and Clinical Governance Group and the BMT Quality group. Any action points are documented in the minutes and reviewed appropriately. Copies of the minutes can be found on the Document Management System.

10. Laboratory testing, collection and processing procedures

10.1 Testing of Product

SOP Title

Expected End-points in the BMT laboratory
Review Procedure for all BMT Harvests

The tests and procedures for measuring, assaying and monitoring properties of the cell products essential to evaluation of their safety and usefulness are described in the relevant SOPs. On completion, the results of these tests are reviewed by the Laboratory Manager. Worksheets are stored in the processing file relating to the patient and product.

The total nucleated cell count, mononuclear cell count, CD34, CFU-GM count and CD3 cell counts in starting and finished products are measured as appropriate, to ensure sufficient cell recoveries in all processes. Specifications have been established with acceptable recoveries for products.

10.2 Tracking of Products

SOP Title

BMT Record Management System

Procedures are in place to allow the tracking and tracing of cellular therapy products. Cellular therapy products can be accurately tracked and/or traced back to the collection centre or forward to infusion/disposal using any or all of the following:

1. Recipient/Donor ID – Patient records, Telepath, Kryotrak database, Stores Database, BMT Database
2. Date of collection – Yearly worksheets, Laboratory diary, Patient records, BMT Database
3. Unique BMT Number – Telepath, Patient Records, Yearly worksheets
4. Unique Collection centre number – Patient records, Yearly worksheets
11. Internal Quality Control in the BMT laboratory

**SOP Title**
CD34 Stem Cell Enumeration by Single Platform using the FACSCANTO™II
Environmental Monitoring in the Cleanroom
Environmental Monitoring Results
Internal Quality Control in the BMT laboratory
Monitoring Microbial Contamination of all Harvested Products

**Flow Cytometer**
CST (Cytometer, Setup and Tracking) beads are performed daily. Results are stored in the film room.

**CD34 Analysis**
CD Chex CD34 control is performed weekly. A CD34 control is also performed after the FACSCanto II has been serviced or if staff are experiencing any problems with the flow cytometer. If the CD34 control is out of range the action taken should be recorded on a Haematology Internal Quality Control Review form. Forms are filed in the BMT Quality manual. Monthly the BMT Laboratory Manager will feedback any quality issues to staff via e-mail.

**Blood Culture Samples**
A blood culture sample is taken post harvest and post processing from all cellular therapy products. All positive results are recorded in the BMT Sterility Results folder found on the Haematology hard drive in a folder labelled BMT. This will highlight any increase trends. An investigation of errors, accidents and adverse events in the BMT laboratory is instigated. See SOP Monitoring Microbial Contamination of all Harvested Products. The investigation should include the cause of the positive culture result if known. The collection and processing events should be evaluated to determine if there was a breach of sterility. Donor records should be evaluated to see if there was any evidence of sepsis at time of collection. The environmental monitoring results should be reviewed to see if the personnel sessional results are negative (settle, contact and finger dab plates)

Once a month the sterility results are reviewed by the Laboratory Manager. A report is made with any actions taken using the Haematology Internal Quality Control review form. Reports are kept in the BMT Quality folder.

Positive results are discussed at the BMT Quality meeting and the Audit, Quality and Clinical Governance Group. A Quality and Training e-mail is sent to staff monthly in which positive culture results and actions taken are discussed.

Yearly an audit is carried out on positive cultures isolated from cellular therapy products. The audits are presented at the BMT Quality meeting and Blood Science Audit, Clinical Governance and Quality Group. Any action points are documented in the minutes and reviewed appropriately. The minutes are available on the Document Management System notice board. Copies of the report can be found in the Audit file in the BMT laboratory.

**Environmental Monitoring Results**
Environmental monitoring in the BMT laboratory includes:

1. Weekly monitoring of the cleanroom in terms of particle and microbial counts.
2. At rest and in use monitoring of the cabinets in terms of particle and microbial counts.
3. Finger dabs of the BMS post processing
4. Quarterly monitoring of the cleanroom and cabinets by Quality Control North West (QCNW).
5. Yearly validation of the pass through procedure by QCNW.

See Environmental Monitoring in the Cleanroom SOP. All results are stored in the appropriate file in a folder labelled Environmental monitoring, found on the Haematology hard drive in a folder labelled BMT.

The BMT Laboratory Manager or in their absence the deputy should review all environmental monitoring results. Any out of limit results must have an Environmental Monitoring Deviation Report form completed. See SOP Environmental Monitoring Results.

The review should include:
- Compliance with monitoring schedule
- Trends showing potential drift from normal environmental monitoring baselines
- Trends of results exceeding alert limits
- Out of specification results
- Significance of Micro Organisms grown (e.g. Gram negative such as Ecoli, Pseudomonas or any unusual organisms identified)

The results should be subject to trend analysis to enable deterioration of standards to be identified.

Where results require immediate corrective actions, the BMT Laboratory Manager will implement them without undue delay. It may be appropriate to seek advice from QCNW. Trend reports can be generated by QCNW and sent to assist in further investigations.

Once a month all Environmental Monitoring Deviation reports are reviewed by the Laboratory Manager. A report is made using the Internal quality control form and any action taken recorded. Reports are kept in the BMT Quality folder. A Quality and Training e-mail is sent to staff monthly in which any out of limit results and actions taken are discussed.

12. External Quality Control in the BMT laboratory

SOP Title
NEQAS CD34 Stem Cell Enumeration Scheme

The BMT laboratory participates in UK NEQAS CD34+ Stem Cell Enumeration scheme. Stabilised peripheral blood obtained from consenting patients, following stem cell mobilisation is used within this programme. Laboratories are requested to report both percentage and absolute values but only the CD34+ stem cell absolutes are scored. The sum of the scores for the last 3 samples is then used to give the overall performance score for a participant. Yearly NEQAS send a minimum of 4 trials and up to a maximum of 6 trials.

The most recent NEQAS results are displayed on the laboratory notice board. All past NEQAS results are filed. On receipt the BMT laboratory manager will review the NEQAS results and document any action required on an External Quality Control Review form. All NEQAS failings are reported as internal errors using the Internal error form. A Quality and Training e-mail is sent monthly to all BMT staff informing them of NEQAS results.

Any problems encountered with NEQAS results are evaluated at the BMT Quality meeting. NEQAS reports are reviewed at the annual management review meeting.

NEQAS is used as a proficiency testing scheme for CD34 analysis. A record of the BMS performing NEQAS is recorded at the front of the NEQAS file. All staff should perform NEQAS on a regular basis.
Despite the use of standardized media significant variability in CFU-GM assay results performed by individuals still hinders the ability to directly compare CFU-GM data. This variability has been associated with both sample preparation and differences in colony identification and enumeration. In order to address the issues arising from the variability encountered in these two areas the BMT laboratory is enrolled on a Colony Proficiency Testing Programme. Participants in this programme focus on colony identification and enumeration, as well as upstream events including cell thawing, dilution, inoculation and plating. The programme runs bi-annually.

13. Equipment/Supplies and Reagents

13.1 Equipment

SOP Title
Procedure to be followed if the Oxygen Depletion Monitor Alarms
Cleanroom maintenance
Calculation of Time required for the Irradiation of Blood and Platelets
Manual Mononuclear Cell Separation using the Cobe Spectra
Use of the Kryo 560-16 Programmable Freezer
Validation of equipment, processes and reagents in the BMT laboratory

Service and maintenance contracts for critical equipment are supplied by the manufacturers or approved suppliers. Service records for all critical pieces of equipment are kept in the Service/Maintenance file in the BMT laboratory. All service results should be checked with the engineer before they depart. Sign the record sheet to confirm compliance. After each visit the date the next service is due is recorded on the BMT Instrument Service Record file, located in the BMT folder on Haematology Hard drive. A copy is printed and stored in the front of the maintenance file. A reminder of the next service date is recorded in the laboratory diary. A label is placed on each piece of equipment to record the date of the last service and the date the next service is due.

It is essential to be able to trace each piece of equipment used in the processing of any material. The installation date of each piece of equipment is recorded at the front of the Service/Maintenance file. In the case of multiple pieces of equipment e.g. Class II Laminar Flow Cabinets, Cobe Spectras the relevant serial number of the piece of equipment used is recorded on the appropriate worksheet.

A record of downtime of each piece of equipment is kept at the front of the Service/Maintenance file. A record of any in house fixes is also recorded. The Record of Downtime for BMT Equipment form is also used to confirm validation of a piece of equipment for use post service or repair.

In addition to scheduled maintenance, the haematology analyser and flow cytometer are calibrated and checked using controls at defined intervals by Routine Haematology/ Cytology laboratory staff using appropriate methods. The information is recorded. Maintenance contracts include call-out to deal with any unexpected problems identified by these checks.

There are procedures in place for the validation of new equipment.

13.2 Supplies and Reagents

SOP Title
Reagent Monitoring and Record Keeping
Reagent Monitoring and Record keeping SOP describes the procedure for ordering, storage and use of supplies and reagents in the BMT laboratory. From these records the BMT laboratory can identify the batch number and expiry date of all reagents in use in the laboratory at any one time.

There is a procedure in place to ensure that all products are suitable for use in the laboratory. All critical reagents must be CE marked.

All procedures have an appropriate consumables record worksheet, where the batch numbers, quantity and expiry dates of all consumables are recorded.

14. Review of processing records

**SOP Title**
Review procedure for all BMT harvests
Release and Exceptional Release of Cellular Products to the Ward
Investigation of errors, accidents and adverse events in the BMT laboratory

The Laboratory Manager reviews all records pertinent to a collection and authorises their release for use. All processing records are reviewed in a timely manner to ensure that any errors are detected as rapidly as possible. Records are reviewed immediately in cases where an error would potentially cause a serious adverse event. Such records should be reviewed by a second member of the BMT laboratory not involved in the processing. When this is not possible, records can be checked by the same individual a second time. Other records must be reviewed at a reasonable time after processing. The review procedure is recorded on the appropriate review worksheet. Until all results are complete the records are held in a ‘Processing records awaiting review’ folder. On completion of all results the records are reviewed by the Laboratory Manager before transfer to their long term storage file. During this review, units that do not meet the required standards will be identified. If all end points are met the review form is annotated to confirm by placing a circle around ‘met’, signing and dating the form. If the end points are not met the ‘not met’ is circled, the criteria is identified in the comments section and exceptional release allowed or not by circling ‘Yes’ or ‘No’. If the exceptional release relates to a technical or clerical reason this can be done by the BMT laboratory manager. However, if the failed criteria may affect the clinical efficacy of the product the BMT Consultant must authorize the exceptional release. See SOP Release and Exceptional Release of Cellular Products to the Ward. Any follow up action resulting from the review procedure is documented at the bottom of the form. Any errors, accidents or adverse events identified during the review procedure are investigated as per SOP Investigation of Errors, Accidents and Adverse Events in the BMT laboratory.

15. Non-Conforming Units

**SOP Title**
Release and Exceptional Release of Cellular Product to the Ward

Products that fail to reach the release criteria can be released under exceptional circumstances by appropriate personnel.

If the product fails to meet the release criteria due to technical or clerical reasons they can still be authorized for release by the Laboratory Manager or Deputy.

Examples include:

- Missing signature in processing records.
- Inadequate CD34 cell dose for allogeneic transplants (<4.0x10⁶/Kg). In this scenario additional stem cells from the donor would be harvested the following day.

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• Poor CFU-GM results if the CD34 cell dose is adequate.
• Container is compromised.
• Error with recipient or donor documentation. Any discrepancies must be resolved and documented prior to issue of the product.

If the product fails to meet the release criteria and the failed criteria may affect the clinical efficacy of the product the BMT Consultant must authorize the exceptional release. Examples include:

• Inadequate CD34 cell dose (<3.0x10^6/Kg)
• Positive sterility result. If the culture is positive an error form should have already been completed. The Consultant should sign the error form and indicate if the product is fit for release.
• Poor viability (<80%).
• >20mls red cells in major ABO mismatched HPC collection.
• Donor ineligibility. This would be highly unlikely as the donor has seen an independent medic pre harvesting. However if the donor was deemed ineligible a record must be made of the reason for their ineligibility on the appropriate review worksheet. The BMT Consultant must authorise the urgent medical need and approve of its issue.

The Consultant must sign and date the exceptional release section on the appropriate review form to indicate medical approval to proceed. Write the Consultant name on the Authorised for Exceptional Release section on the Release of Product for Reinfusion worksheet.

16. Errors, Accidents and Adverse Event

SOP Title
Investigation of Errors, Accidents and Adverse events in the BMT laboratory.
Error Logging

It is essential to report any errors, accidents and adverse events/reactions in the BMT laboratory, in a timely fashion, to key individuals so that any appropriate corrective action can be taken. The timely review of processing records will ensure that isolated and/or systematic errors are detected as rapidly as possible. This is an essential part of the Quality system used to ensure all product, service and process failures and near misses are reported, processed and acted upon in a timely and consistent manner.

All BMT laboratory staff are responsible for bringing any errors, accidents or adverse events/reactions to the attention of senior staff promptly.

An error is a mistake, inaccuracy, deviation.

An accident is unexpected event especially one causing damage.

Serious Adverse Event (SAE) is defined as “any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of cells intended for human application and which, in relation to a donor or recipient of 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, hospitalization or morbidity”.

Serious Adverse Reaction (SAR) is defined as “an unintended response, including a communicable disease, in a donor of cells intended for human application or a recipient of cells, which may be associated...
with the procurement or human application of cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs hospitalization or morbidity”.

‘Near Misses’
Events which are commonly referred to as ‘near misses’ should be reported as serious adverse events if any of the above criteria are met.

**Adverse reactions reportable to the Human Tissue Authority (HTA)**
Any serious adverse reaction in a donor which may influence the quality and/or safety of cells should be reported to the HTA.

Any serious adverse reaction in a recipient observed during and/or after clinical application which may be linked to the quality and safety of cells should be reported to the HTA.

Suspected serious transmitted infections (e.g. bacterial, fungal, viral, prion, parasitic) should always be reported to the HTA.

It is the responsibility of the BMT laboratory manager or their deputy to review and report all errors, accidents and adverse events.

All errors, accidents and adverse reactions are documented and subsequently investigated by the BMT laboratory. Errors, accidents and adverse reactions are also reviewed and signed by the Departmental Quality Managers and the appropriate BMT Consultant. A copy of the report is kept with the patients processing records and in the Errors, Accidents and Adverse reactions file located in the BMT laboratory.

A record of all errors is recorded, in date order, in the BMT Error log book located in the BMT Laboratory Room 2028. Any error, accident or adverse event is discussed at the monthly Blood Science Audit, Quality and Clinical Governance meeting and the BMT Quality meeting and any action noted. The error book is reviewed by the BMT Laboratory Manager/BMT Quality representative before these meetings to identify any trends. Any identified trends noticed require a full Root Cause Analysis. If a trend, in the BMS involved in the error, is noticed re training must be instigated. Errors, accidents and adverse reactions are also reviewed by the Departmental Quality Managers on a monthly basis.

A Quality and Training e-mail is sent monthly to all BMT staff informing them of any errors, accidents and adverse events and actions taken.

Clinical Incidents/Accidents should be reported via DATIX. See Error Logging SOP.

**17. Labels**

**SOP Title**
Product Labelling

Labelling operations are conducted in a manner adequate to prevent mislabelling of components.

Each component has a number unique to the product. Product labels are printed on demand. The labels are printed directly from the DMS ensuring the current version of label is always used.

Labels currently in use are deemed ‘fit for purpose’. Introduction of new types of label will require validation for ‘fit for purpose’. Validation must ensure that each label is in compliance with the template and
the label is reliable for storage under the conditions in use. Validation of the labels must be approved by the Laboratory Manager before the labels are issued.

**Labels used in the BMT Laboratory**

**Labels applied to fresh Cellular Therapy Products at completion of processing, at distribution and during transport.**

1. Fresh Allogeneic HPC, Apheresis
2. Fresh Allogeneic HPC, Marrow
3. Fresh Allogeneic HPC, Cord Blood
4. Fresh Autologous HPC, Marrow
5. Fresh TC- T cell

**Labels applied to cryopreserved Cellular Therapy Products at completion of processing, at distribution and during transport.**

6. Cryopreserved Allogeneic HPC, Apheresis
7. Cryopreserved Allogeneic HPC, Marrow
8. Cryopreserved Allogeneic HPC, Cord Blood
9. Cryopreserved Autologous HPC, Apheresis
10. Cryopreserved Autologous HPC, Marrow
11. Cryopreserved TC- T cell
12. In addition to labels 6 to 11 a hand written base label is heat sealed into the pocket provided on the Cryogenic bags.

**Biohazard Labels applied to Cellular Therapy Products at completion of processing, at distribution and during transport.**

13. Biohazard
14. Allogeneic Cellular Therapy Product from a known High Risk Donor
15. Virology Screen Unavailable
16. Positive result for ….

**18. Inspection of products prior to distribution**

**SOP Title**

Release and Exceptional Release of cellular products to the ward.

Thawing Cells for Therapeutic Use on the ward

Infusion of Bone Marrow/Peripheral Blood Stem Cells (PBSC) (cryo and non-cryo preserved).

Circular of Information for the use of Cellular Therapy Products

There is a procedure in place for the inspection of products to be issued for infusion. This requires 2 members of staff to check the product identification and labeling and the integrity of the packaging. Both members of staff must sign and date the Release of Product for Reinfusion form to confirm all the checks are in place. In the event that there is a discrepancy relating to the product or recipient, or the packaging has been compromised, the laboratory manager or BMT Consultant must give authorization for use.

The Circular of Information for the use of Cellular Therapy Products is used for the infusion of cellular therapy products to ensure that the quality of the product is maintained. The department also has a policy to **Do not photocopy this document**
be used for the infusion of a stem cell product (Infusion of Bone Marrow/Peripheral Blood Stem Cells (PBSC) (cryo and non-cryo preserved). This policy describes the use of the products, indications, contraindications, side effects and potential hazards together with dosage indications. A copy of the Circular is available on the ward, in the BMT transport boxes and dry shipper.

A laboratory report is issued with each product reinfused, detailing information relating to the product and handling instruction. Records are made and maintained of the following:

- Date and time of transit to the recipient
- The name and unique identifier of the intended recipient
- The proper product name and product identifier
- Acknowledgement of receipt by the nursing staff caring for the patient
- Temperature during transit.

An information sheet detailing information relating to the product including handling instructions is available in the transport box/dry shipper.

19. Product Recall

**SOP Title**
Recall Procedure

Following the issue of cells should an error or problem with bags or paperwork be identified that impacts on the quality or safety of the product, then these products must be located and returned to the laboratory, until the issue is resolved. A policy (Recall Procedure) is available relating to the return of products from issue.

The two most important parts of the recall procedure are:

- The speed with which it is carried out
- The clarity of the instructions given

The return of any product issued is a deviation from the SOP and requires a detailed report and risk assessment from the laboratory as to the cause and actions taken to ensure product safety.

20. Conditions for storage

**SOP Title**
Conditions for the Storage and Disposal of Harvested material.

Bone Marrow, Peripheral Blood Stem Cells, Cord Stem Cells and Donor Lymphocyte harvests can be stored short-term at temperatures of 2-8°C or long-term in the vapour phase of liquid nitrogen at temperatures of <-135°C.

20.1 Conditions for short-term storage

**SOP Title**
MONIKA Temperature Monitoring System

Each harvest if at all possible should be frozen or transfused on the day of collection. If this is not possible the maximum time period for storage before freezing or transfusing is 72 hours from the end of the collection. Cell counts are adjusted to <200x10⁶/ml with autologous plasma or 4.5% HAS.
The cells are stored on a designated shelf in a blood transfusion fridge. The shelf must only be used to store stem cell, donor lymphocyte collections or related products. The blood transfusion fridge is connected to the MONIKA™ temperature control system. This system automatically records temperature and sounds an alarm when temperature limits are exceeded. MONIKA™ pc software enables continuous monitoring of all networked temperature probes. Logged data is downloaded to the pc from the Network Master Unit. Cabinet temperature history records are updated on a continuous basis; alarms are generated in the form of a pop up screen.

20.2 Conditions for long-term storage
Cells are cryopreserved using a controlled cooling rate in a medium containing 10% dimethyl sulphoxide in either autologous plasma or human albumin solution. The final cell concentration after addition of cryoprotectant is <100x10⁹/L.

Frozen material should be stored at a sufficiently low temperature to ensure recovery of living cells after the intended preservation period. Cells are stored in the vapour phase of liquid nitrogen at ≤–135°C. The vapour phase of liquid nitrogen is used to reduce the risk of cross contamination.

All harvested material is stored in one of 5 storage tanks located in the BMT laboratory. The tanks are supplied with liquid nitrogen piped into the laboratory from a cylinder outside the Duncan building into an inlet in the wall. Each storage tank automatically fills with liquid nitrogen when the low-level fill is reached. As a safety measure the BMT laboratory is fitted with an Oxygen Depletion Monitor and extractor fan.

20.21 Storage Tank Alarm Monitoring systems
The liquid nitrogen storage tanks are on a yearly service contract. This involves 1 visit per year. Records from each visit are kept in the Service/Maintenance file in the BMT laboratory. After each visit the date the next service is due is recorded on the BMT Instrument Service Record file, located in the BMT folder on Haematology Hard drive. A copy is printed and stored in the front of the maintenance file. A reminder of the next service date is recorded in the laboratory diary.

Each tank has a high and low temperature alarm and a high and low liquid nitrogen level alarm.

Each tank undergoes daily and monthly checks to ensure there is no drift in temperature, liquid nitrogen levels, liquid nitrogen use and that the tanks fill automatically at the designated liquid nitrogen level.

20.22 Contronics Alarmlog

SOP Title
Contronics Alarmlog

The temperature of the storage tanks is continually monitored using the Contronics alarmlog. The Contronics alarmlog is an accurate temperature monitoring and logging system. It provides continuous logging of temperatures and events at defined intervals. When used in conjunction with PC analysis software temperature records can be automatically produced to meet statutory requirements for storage of frozen material. The system is set to alarm at a low temperature of −196°C and a high temperature of −110°C. Annually the 6 Alarmlogs are calibrated by the laboratory. Contronics also perform Alarm limit testing of each Alarmlog annually to ensure each Alarmlog alarms at the designated temperature.

21. Transportation

SOP Title
Transportation of non-cryopreserved or cryopreserved collections

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DMS Ref: Blood and Marrow Transplant Quality Management Plan.doc
21.1 Transportation of non-cryopreserved collections
All non-cryopreserved harvests are transported at room temperature within validated insulated clearly labelled designated containers. A clearly marked contact Name, Address and Telephone number of the sending and receiving centre is attached to the container. Products are always accompanied by a BMS. The primary product container is placed in a secondary plastic bag and sealed to prevent leakage. The temperature inside the transport box is monitored during transit. A temperature of 2°C to 25°C must be maintained during transit. The temperature during transit is recorded on the BMT Collection and Delivery Record Form and/or Release of Product for Reinfusion form.

21.2 Transportation cryopreserved collections

SOP Title
Thawing Cells for Therapeutic Use on the ward.
Use of the Dry Shipslog Temperature Alarm Data Logger

Cryopreserved products are transported in dry shippers that have been validated and contain sufficient absorbed liquid nitrogen to maintain the temperature below $-135^\circ C$ for 48 hours beyond the expected infusion time. A designated dry shipper is available in the laboratory as well as a designated high-risk container. The cryoshipper is clearly labelled. A clearly marked contact Name, Address and Telephone number of the sending and receiving centre is attached to the container. Products are always accompanied by a BMS. The dry shipper is fitted with a DryShips LOG Temperature alarm and datalogger which records the temperature in the dry shipper during transit. Records of the temperature are maintained in the processing records for each product issued.

22. Disposal

SOP Title
Policy for Discarding Previously Harvested Cells
Conditions for the Storage and Disposal of Harvested Material

There is a written policy for the disposal of HPC components to ensure that the laboratory storage inventory only contains items for which there is a continuing clinical need. This helps to maintain capacity to meet the continuing patient need. It is the policy of the RLBUH to discard material on the death of the intended recipient or after a minimum of 5 years storage if the consultant feels there is no further clinical need with appropriate consent.

Death of a patient can only be assured if one of the following applies:

- A letter from the referring consultant giving dates and cause of death.
- A date and cause of death on the master BMT database.
- A record of death on the hospital IPM system.

A BMT Consultant must approve any material to be discarded.

23. Records

SOP Title
Management of Data and Information for Blood Sciences
BMT Record Management System
The document Management of Data and Information describes the procedure in place for the proper management of data and information in the department. The laboratory computer system is provided by iLab TP (Telepath). The iLab.TP (TelePath) system has a highly configurable control of permissions and access to functions. It is based around laboratory sections, “privilege levels” and system functions. Every user has a unique identifier for their sole personal use and assigns and manages their own password. The patient administration system is provided by iPM.

There is a designated IT Manager and Deputy for the Department, who liaise with both the Trust IT Department and the JPS IT Manager. Also IT issues are discussed as an agenda item in the Laboratory Management Committee meetings.

The following documents are available in the department and/or on the Trust Intranet.

- CPA Standard D2 – Management of Data and Information
- Data Protection Act, 1998, Legal Guidance (Room 2027)
- Caldicott Report (Room 2027)
- Trust Informatics Policy
- Trust Records Management Policy
- Information Management and Technology Security Policy
- Trust Information Assurance Policy
- Data Quality Policy
- Personnel Information – Confidentiality Policy
- Personnel Information – Confidentiality Procedure Document
- Trust Fax Policy
- Computer Antivirus Management Policy

23.1 Availability of Data and Information to Users
The system provides the laboratory and its user’s access to patient laboratory results.

Hardcopy reports and/or electronic reports are produced and delivered to requesting locations. Results are available in response to telephone enquiries or requests.

All wards and departments within the Royal Liverpool University Hospital have access to authorised results online via the ICE reporting system.

Previous results are available to laboratory staff during processing of samples. This facilitates interpretation and validation of current results. The system uses delta and abnormal range checking to highlight unexpected and/or changes in patient results.

Systems are in place for the flexible retrieval of information for workload statistics and audit procedures.

Security
Two stage login procedure for access into Telepath laboratory computer system via Network PCs or dumb terminals. Stage one is input of unique user ID and stage two is input of password. Passwords are required to be changed every 90 days.

Access
Two stage login procedure. There are 9 user privilege levels. These control which procedures are available to users. Privilege levels are set after discussion with section managers.
Confidentiality and Data Protection

All staff are made aware that as part of their terms of employment, it is their responsibility to confidentiality. Staff induction programme also covers patient confidentiality.

All staff receive training on their legal obligation under the requirement of Caldicott principles and Data protection Act. Training sessions are given by the Departments Caldicott and Data Protection Co-ordinator. Regular Data Protection lectures are also run by the Trust.

Backup System

Resilience is built into the system by having a second computer, which is configured to automatically take over should the first fail.

Data is continuously backed up onto a second set of mirrored disks (RAID 10).

Data is backed up onto tapes on a daily basis and stored in a location separate from the main Telepath server.

Storage, Archive and Retrieval

Disposal of request forms and worksheets with patient information and data is into green bags. The contents of which are shredded.

Obsolete PC equipment is disposed through the Trusts IT Department, who remove hard disk drives when necessary from PCs.

Breakdown of IT Systems

There is sufficient access to information in the laboratory to continue the provision of the BMT service if the IT System was down for any length of time:

1) All cryopreserved products can be located using the printout of the stores database or the record of the storage position in the storage book.
2) There are hardcopies of all current and past patient worksheets and results in the laboratory.

Fax Policy

There is a ‘no fax policy’ for sending results. When faxing for other purposes all staff adhere to the Trust Secure Transfer of Information Policy.

23.2 Pre Examination Records

Request forms

When the request card and sample are received in the Department, they are assigned the same unique laboratory number. Patient details and test(s) requested are entered into the laboratory computer system.

Electronic copies are stored indefinitely on the laboratory computer system and can be accessed by authorised staff only. The paper request forms are kept for the minimum retention period, they are stored in the individual laboratories/offices within the Department.
23.3 Examination Records

**BMT Worksheets**
Results from all cellular therapy products are recorded on BMT worksheets. Records are stored in such a manner as to maintain efficient retrieval.

Worksheets are filed by name and date. Records recorded on forms have a unique form number. Each collection has a unique ID number assigned to it.

Worksheets are kept in appropriate labelled files, access to which is limited as access to the Department is restricted to authorised personnel.

At RLUH access is limited by the use of an intercom and swipe card system. The Department is also alarmed and has CCTV cameras at the entry doors. The BMT laboratory door is locked outside normal working hours.

**Standard Operating Procedures**
Withdrawn SOP’s are held indefinitely.

**Internal QC Records**
Internal QC records are easily retrievable and kept permanently in the BMT laboratory as a paper record

**Batch Records**
Batch records of all reagents and control materials are kept permanently in the BMT laboratory as a paper record. From these records it is possible to identify any stock currently in use.

**Maintenance/Service Records**
Maintenance and service records of all instruments are kept for the lifetime of the instrument in the BMT laboratory.

23.4 Post Examination Records

**Reports**
Computer generated paper copy of the test report is sent to be filed in the patients case notes. The electronic copy is held permanently attached to the patient’s record.

**Telephoned Results**
A record of telephoned results is kept electronically.

**Quality Records**

**Internal Audit**
Internal audit reports are stored in an appropriately labelled file in the audit officer’s laboratory. They are kept for a minimum of 10 years. A copy of all BMT audits is kept in the laboratory.

**Quality Improvement**
Records of quality improvement notes are also kept in the audit file. These records are kept for a minimum of 10 years.
23.5 Records of External Origin

External QC Records
These records are stored in files in the BMT laboratory. These are kept for a minimum of 2 years.

All current records are displayed on a QC notice board.

Accreditation Visit Reports
These reports are kept in an appropriate labelled file in the Directorate Manager’s office. They are kept for 10 years.

Health & Safety Reports
These reports are kept by the Health and Safety Officer. They are kept for a minimum of 10 years.

24. Quality Improvements
A quality management system has been set up to review current practices and identify areas in which the BMT laboratory needs to improve. Continual quality improvements are an essential part of maintaining and improving the transplant service. This is an ongoing process.

24.1 Evaluation and Improvement Processes
It is important to identify the causes of errors so that the appropriate steps may be taken to prevent them from recurring.

All errors, accidents and adverse reactions are documented and subsequently investigated by the BMT laboratory. Errors, accidents and adverse reactions are also reviewed and signed by the Departmental Quality Managers and the appropriate BMT Consultant. A copy of the report is kept with the patients processing records and in the Errors, Accidents and Adverse reactions file located in the BMT laboratory.

A record of all errors is recorded, in date order, in the BMT Error log book located in the BMT Laboratory Room 2028. Any error, accident or adverse event is discussed at the monthly Blood Science Audit, Quality and Clinical Governance meeting and the BMT Quality meeting and any action noted. The error book is reviewed by the BMT Laboratory Manager/BMT Quality representative before these meetings to identify any trends. Any identified trends noticed require a full Root Cause Analysis. If a trend, in the BMS involved in the error, is noticed re training must be instigated. Errors, accidents and adverse reactions are also reviewed and signed by the Departmental Quality Managers on a monthly basis.

24.2 Internal Audit of Quality Management System

Title
Internal Quality Audit SOP for Auditors and Auditees
To demonstrate that the Quality Management System has been effectively established, it is subject to planned and scheduled internal audit. This is conducted against agreed criteria and carried out by personnel trained in internal audit. The record of this process includes the activities, areas or items audited, any non-conformities found and also recommendations and time scale for corrective and preventive actions.

The records of internal audit are regularly evaluated and the decisions taken documented, monitored, reviewed and acted upon.
24.3 Internal Audit of Examination Process

Internal audit of pre examination, examination and post examinations processes is necessary to ensure that they are being conducted according to agreed, tested procedures.

As it is recognised that the individual must be trained in audit, the Department has attended formal audit training. Members of the Department have received this training and an audit officer has been appointed.

24.4 External Quality Assessment

Participation in EQA reassures both providers and users that a quality service is being provided.

24.5 Assessment of User Satisfaction and Complaints

Title
Assessment of User Satisfaction
Departmental Complaints Procedure

Assessing user satisfaction and monitoring complaints is essential to establish whether the service meets the needs and requirements of the users. The BMT Laboratory Manager has compiled a user satisfaction questionnaire to seek the views and comments of its users. Intermittently a user satisfaction survey will be distributed to the Bone Marrow Transplant wards. The comments of the users are recorded, reviewed and acted upon where appropriate.

There is a policy and procedure for managing complaints. A complaint is an expression of dissatisfaction with some aspect of the service provided and can be made by a user, patient, relative, visitor or carer. The Trust is committed to minimizing complaints, but where people wish to register their dissatisfaction an investigation will take place. The departmental complaints procedure describes the action to be taken on the receipt of a complaint whether written, telephoned or personally delivered.

External incidents and complaints investigations are kept in the appropriate file in the Directorate Manager’s office.

User satisfaction and complaints, together with performance targets form part of the annual laboratory review with the Trust Executive Director. The Department via the Clinical Director participates in the evaluation of clinical effectiveness, audit and risk management activities of the trust.

24.6 Staff feedback

Monthly the BMT Laboratory Manager will send an e-mail to all BMT staff regarding Quality issues in the BMT Laboratory, including any errors, NEQAS results, QCNW out of limit results. All minutes to all meetings including the BMT Quality committee meetings and Audit, Quality and Clinical Governance Group are available on the DMS.

A Quality Bulletin is posted on the Blood Science noticeboard monthly by the Quality Managers to inform staff of current quality issues.

24.7 Annual Quality Report

Yearly the BMT Laboratory Manager will send an annual Quality report to the Transplant Director, Transplant Consultant, Transplant Co Ordinator, Ward Sister.
25. Service Level Agreements
A Service level agreement has been drawn up between RLBUH and Alder Hey Children’s Hospital for the provision of the BMT Laboratory Service. This is reviewed annually. Similarly service level agreements are available between NHS BT, ANBMT and WBMDR and RLBUH. These are reviewed annually by the respective organizations and signed copies sent to RLBUH.

26. Contingency Plan

**BMT Title**
Contingency Agreement with Central Manchester University Hospital
BMT Emergency Plan

A contingency agreement is in place between RLBUH and Central Manchester University Hospital NHS Foundation Trust to provide a continuation of the Stem Cell Transplantation Service at RLBUH and Central Manchester in the event of either Trusts inability to process.

A BMT emergency plan is also available. This document describes:

1. Procedures to be followed and the contingencies available to ensure that BMT Laboratory services can be continued in emergency situations, namely unavailability of BMT staff, equipment failure, and transportation problems.

2. Procedures to ensure the continued storage of cryopreserved cells within a Human Tissue Authority licensed establishment should the BMT Laboratory permanently terminate its activities.

3. Procedures to ensure the maintenance of all records in compliance with legislation should the BMT Laboratory permanently terminate its activities.