SITE QUALITY MANUAL

Northern Ireland Blood Transfusion Service
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<th>Description</th>
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</tr>
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</table>

### 5 Measurement / Analysis / Improvement

<table>
<thead>
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<th>Description</th>
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<tr>
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</tr>
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<td>5.9</td>
<td>Analysis of Data</td>
</tr>
</tbody>
</table>

### 6 Quality Management System Cross Reference

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
</table>

### 7 Change History

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
</table>
1 Management Responsibility

The Northern Ireland Blood Transfusion Service (NIBTS) has a commitment to the development and implementation of a Quality Management System to comply with the requirements of:

- Human Tissue (Quality and Safety) Regulations 2007
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors
- Clinical Pathology Accreditation (UK) Ltd
- Controls Assurance Standards as applied within the DHSSPS in N Ireland

This Quality System is described in this document. The document also aims to satisfy the requirements of a site Master File as required by the MHRA.

This commitment is further demonstrated by documenting, implementing and communicating to all employees the following:

- Our policy for Quality
- Quality Objectives
- Performing annual management reviews
- Identifying and communicating applicable regulations including those identified above
- Ensuring that resources are available to deliver our Quality Policy

1.1 Organisation Overview/General Information

Company Details

Name: Northern Ireland Blood Transfusion Service
Belfast City Hospital Complex
Lisburn Road
Belfast
BT9 7TS

Telephone - 02890 321414,
Outside Normal Business Hours - 02890 329241
Facsimile - 02890 439017

The Northern Ireland Blood Transfusion Service is sited adjacent to the Belfast City Hospital and one mile from the Royal Victoria Hospital (the N. Ireland Trauma Centre) in Belfast, these two hospitals being major teaching units. The site expands to two acres. The facility at the Belfast City Hospital Complex includes a Blood Collection Unit (primarily apheresis). In addition the Service operates a permanent Blood Collection Unit in the centre of Belfast, and three mobile blood collection teams. One of these teams
operates from a base located in the Tyrone and Fermanagh Hospital, Omagh, another operates with a specifically designed and built mobile collection facility ("Blood Mobile")

The NIBTS site is close to the motorway network facilitating access to all main roads and on to towns in which all hospitals supplied by the Service are sited.

The Northern Ireland Blood Transfusion Service collects and processes approximately 54,000 whole blood and 4500 apheresis donations annually.

The main products manufactured are Whole Blood, Red Cell Products, Platelet Concentrates, Cryoprecipitate, Fresh Frozen Plasma for Clinical Use. Some of these products are produced in small volume forms for use in paediatric transfusion. All red cell, platelet and frozen plasma products for clinical use are leucodepleted. NIBTS aim to issue 90% of platelets as apheresis. All platelets issued are tested for the presence of bacteria

Therapeutic Products are produced aseptically in closed systems. Terminal sterilisation in the final container is not performed as this would cause degradation of the products.

On site irradiation is performed on all platelet components and a quantity of red cell components.


The Service provides a range of regional patient testing services. These are: Antenatal Blood Group Serology - This includes Blood Grouping, Red Cell antibody screening and titres, Anti D and Anti c Quantitation.

Antenatal Microbiology - This includes screening for Hepatitis B antigen, HIV antibodies, Syphilis and Rubella immunity

Blood Group Reference Services - This include Red Cell antibody screening and identification, and cross-matching when difficulties are encountered by local hospital blood banks. Provision of phenotyped Red Cells. Screening for platelets antibodies.

Number of employees - NIBTS currently employ approx. 200 employees.
Licensed Activities
MHRA Licensed Activities

The Northern Ireland Blood Transfusion Service is a Registered Blood Establishment with the Medicines and Healthcare products Regulatory Agency and holds a Blood Establishment Authorisation 11437/01. NIBTS also are to licensed to hold and distribute pharmaceutical products and hold a Wholesale Distributors Licence WL11437/01.

HTA Authorised Activities

Umbilical Cord Blood collection process and storage
Establishment: Belfast Cord Blood Bank
Licence number: 11077

CPA (UK) Ltd Accredited activities

Testing of Patient samples for Blood Group Serology and Microbiology markers i.e. HbsAg, HIV, Syphilis and Rubella Immunity

Other Manufacturing Activities
None
# Blood Components Prepared and Issued

<table>
<thead>
<tr>
<th>No</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Leucodepleted Red Cells in Additive Solution</td>
</tr>
<tr>
<td>2</td>
<td>Leucodepleted Autologous Donation Red Cells in SAG-M</td>
</tr>
<tr>
<td>3</td>
<td>a) Leucodepleted Red cells in Additive Solution for Neonatal Use</td>
</tr>
<tr>
<td>4</td>
<td>Leucodepleted Red Cells (CPDA-1). Resuspended in same donor plasma</td>
</tr>
<tr>
<td>5</td>
<td>Leucodepleted Red Cells (CPDA-1) Resuspended in Group Specific Plasma</td>
</tr>
<tr>
<td>6</td>
<td>Leucodepleted Platelets Pooled Buffy Coat Derived - Irradiated</td>
</tr>
<tr>
<td>7</td>
<td>Leucodepleted Platelets, Apheresis - Irradiated</td>
</tr>
<tr>
<td>8</td>
<td>Leucodepleted Platelets Apheresis for Paediatric Use - Irradiated</td>
</tr>
<tr>
<td>9</td>
<td>Leucodepleted Platelets, Apheresis for Neonatal Use - Irradiated</td>
</tr>
<tr>
<td>10</td>
<td>Leucocytes (Buffy Coat) [Concessionary release]</td>
</tr>
<tr>
<td>11</td>
<td>Leucodepleted Fresh Frozen Plasma</td>
</tr>
<tr>
<td>12</td>
<td>Leucodepleted Large Volume Fresh Frozen Plasma (Methylene Blue Treated and Removed)</td>
</tr>
<tr>
<td>13</td>
<td>Leucodepleted Fresh Frozen Plasma for Neonatal Use (Methylene Blue Treated and Removed)</td>
</tr>
<tr>
<td>14</td>
<td>Leucodepleted Pooled Cryoprecipitate (a pool of 5 donor cryoprecipitates)</td>
</tr>
<tr>
<td>15</td>
<td>Leucodepleted Cryoprecipitate for Neonatal Use (Methylene Blue Treated and Removed)</td>
</tr>
<tr>
<td>16</td>
<td>Octaplas (Solvent/detergent treatment [S/D])</td>
</tr>
<tr>
<td>17</td>
<td>Leucodepleted Saline Washed Red Cells</td>
</tr>
</tbody>
</table>

- Other specific components may be irradiated on request and as appropriate.
Site Quality (Master File) Manual

Product Classes handled under the Wholesale Dealers Licence

<table>
<thead>
<tr>
<th>Class</th>
<th>Handling Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large volume sterile liquids</td>
<td>Yes</td>
</tr>
<tr>
<td>Small volume sterile liquids (includes eye drops)</td>
<td>Yes</td>
</tr>
<tr>
<td>Semi-solid sterile dosage forms (includes sterile creams and ointment)</td>
<td>Yes</td>
</tr>
<tr>
<td>Solid sterile dosage forms includes sterile powders</td>
<td></td>
</tr>
<tr>
<td>Other sterile products</td>
<td></td>
</tr>
<tr>
<td>Non-sterile liquids (includes solutions, syrups and suspensions)</td>
<td></td>
</tr>
<tr>
<td>Semi-solid non-sterile dosage forms (includes non-sterile creams and ointments)</td>
<td></td>
</tr>
<tr>
<td>Solid non-sterile dosage forms (includes tablets, capsules, suppositories powders)</td>
<td></td>
</tr>
<tr>
<td>Other non-sterile products</td>
<td></td>
</tr>
</tbody>
</table>

Cord Blood products – Volume Reduced Cord Blood

Activities contracted out to other companies –

Key activities contracted to other bodies are:-

Scottish National Blood Transfusion Service
- Provision of confirmatory testing on a range of microbiological markers.
- Provision of Anti D and Anti C Quantitation

Belfast Health and Social Care Trust
- Confirmatory Testing on a range of microbiological markers and a range of other pathology tests.
- Collection of Cord Bloods
- Provision of Estates Services
- Provision of HR Support Services

Business Services Organisation
- Procurement and Logistics Services
- Legal Services
- Equality and Human Rights Support Services

A wide range of service and maintenance activities relating to plant and equipment are contracted out and are covered by Service Level Agreement and/or contracts as appropriate - See SOP:GL 005.
1.2 Internal Communications

NIBTS have a wide range of committees and groups, which meet on a regular basis. Key committees and groups are identified in the table below. Terms of Reference for these groups are retained and reviewed on a regular basis.

NIBTS Agency Board
NIBTS Agency Board – Audit Committee
NIBTS Agency Board - Governance and Risk Management (GRM)
Senior Management Team
Risk Management (CGRM Sub-committee)
Training and Audit (CGRM Sub-committee)
Quality Improvement Review
Incident Management
Change Management
Information Management and Technology Steering Group.
Health and Safety Committee
Donor Services Team
Blood Donation Co-ordinating Group
Hospital Services
Serology
Microbiology
Cord Blood
Medical Devices and Equipment Group
Waste and Environmental Management Committee
Equality and Human Rights Group

These meetings, supported by a range of other meetings including intradepartmental meetings, which are held on a regular basis, serve to facilitate control, assurance and robust communication processes within NIBTS. These processes are described in the ‘NIBTS Board Assurance Framework Document’ FMW:QD:001.

Meetings have agendas, minutes and action lists, specifically within Laboratories these meetings are managed in Keeping with SOP:LS:004 ‘Procedure for the Management of Laboratory Meetings’.

The links between the various meetings are set out in the schematic on the next page.
Figure 4 – Assurance Framework

Audit Committee
- Statement internal Control
- Audit Reports
- External Audit
- Internal Audit
- Internal Assurances,
- Financial and non-Financial reports

Agency Board

Governance & Risk Management Committee
- Governance & Risk Management Reports

Chief Executive Report

Senior Management Team
- Corporate Management
- Corporate Governance
- Business and Operational Planning
- Corporate Development

Subgroups
- Governance & Risk Management subgroup
- Controls Assurance Standards
- Health & Safety Group* 
- Adverse Incident Management
- Claims Management
- Learning & Development & CPD
- Clinical Audit & Research
- Quality Management System
- User Groups (hospital, donors)
- Complaints Management
- Information Governance
- Research Governance
- Medical Devices and Equipment Group

Functional Groups, Medical, Support
Operational, Regulation / Quality
- Blood Donation Coordinating Group
- Laboratory Groups
- Quality Group reports
Other Assurance Reports, including Departmental reports, for example: Finance, MHRA, HTA, CPA, RQIA. Other information will include minutes of relevant meetings.

*Health and Safety Committee – includes representatives from all departments including the Laboratory Training Officer who has responsibility for Laboratory H&S
1.3  Management Representative

The Quality Manager is the Nominated Quality Management representative in relating to CPA, UK Ltd and HTA Representative and has responsibility (directly or indirectly) for ensuring that the processes required for the quality management system are established, implemented and maintained in accordance with the relevant Standards.

The Regulatory Affairs and Compliance Manager (BSQR Responsible Person) takes a specific lead on key aspects of the quality system demonstrating the significant of compliance with BSQR and their role in assuring compliance with this and relevant GMP standards. This individual has specific responsibility for the following aspects of the Quality Management System:

- Incidents (CAPA)
- Change Control
- Validation
- Document Control
- Recalls – specifically those of Blood Components
- GMP Training
- Internal Audit associated with BSQR/GMP compliance

The Regulatory Affairs and Compliance Manager and the Quality Manager will work together to provide a Quality Function within NIBTS. Each Manager will respective to their roles and responsibilities ensure appropriate review of quality targets and objectives at relevant operational meetings.

The Regulatory Affairs and Compliance Manager will be responsible for:

- Reporting on the performance of the quality system and any need for improvements to top management at the monthly management review of the system and provide reports to the Board

The Quality Function will be responsible for:

- Promoting awareness of and working with employees, consultants and suppliers to assure quality and regulatory compliance.

2  Quality Management System

2.1  Scope of Quality Manual

This Quality Manual describes the quality system applied within NIBTS and aims to satisfy the relevant licensing and accreditation requirements. These are cross-referenced in Section 6 of this document. The Quality Manual sets out the approach to assuring quality. Agency arrangements are in place to assure that business is done impartially and that the quality of work is not adversely affected; these include:

- Human Resource policies and procedures
- Standing Financial Instructions
- The Board Assurance Framework
Site Quality (Master File) Manual

The NIBTS Quality Manual sets forth the Quality Management System to provide donors and patients with products and services that meet or exceed their expectations.

The Quality System is owned by and applicable to all departments with NIBTS. Its delivery is supported by Quality Function which includes the Quality Department and the Regulatory Affairs and Compliance Department.

Quality Function

The Quality Function is responsible for developing and maintaining the Quality Assurance System which is based on the Blood Safety and Quality Regulations, Human Tissue Quality and Safety Regulations, current European Standards for Good Manufacturing Practice and CPA(UK)Ltd standards.

The Quality Department and Regulatory Affairs Department liaise closely on all aspects of the quality system. Each department will take the lead on specific aspects of the quality systems. This is set out in the table below:

<table>
<thead>
<tr>
<th>Area</th>
<th>Lead</th>
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<tbody>
<tr>
<td>Quality System</td>
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<tr>
<td>Document Control</td>
<td>RAC</td>
</tr>
<tr>
<td>Incident Management</td>
<td>RAC</td>
</tr>
<tr>
<td>Change Management</td>
<td>RAC</td>
</tr>
<tr>
<td>Internal Audit</td>
<td>RAC</td>
</tr>
<tr>
<td>- BSQR/GMP</td>
<td>RAC</td>
</tr>
<tr>
<td>- WDL</td>
<td>QM</td>
</tr>
<tr>
<td>- CPA</td>
<td>QM</td>
</tr>
<tr>
<td>- HTA</td>
<td>QM</td>
</tr>
<tr>
<td>- Supplier</td>
<td>QM</td>
</tr>
<tr>
<td>Recalls</td>
<td>RAC</td>
</tr>
<tr>
<td>Validation</td>
<td>RAC</td>
</tr>
<tr>
<td>Strategy</td>
<td>QM</td>
</tr>
<tr>
<td>Equipment</td>
<td>QM</td>
</tr>
<tr>
<td>SABRE</td>
<td>RAC</td>
</tr>
<tr>
<td>Suppliers</td>
<td>QM</td>
</tr>
<tr>
<td>Estates</td>
<td>QM</td>
</tr>
<tr>
<td>Training(GMP)</td>
<td>RAC</td>
</tr>
<tr>
<td>Regulation/Accreditation</td>
<td></td>
</tr>
<tr>
<td>MHRA - BSQR</td>
<td>RAC</td>
</tr>
<tr>
<td>MHRA - WDL</td>
<td>QM</td>
</tr>
<tr>
<td>HTA</td>
<td>QM</td>
</tr>
<tr>
<td>CPA</td>
<td>QM</td>
</tr>
</tbody>
</table>

QM – Quality , RAC Regulatory Affairs and Compliance
2.2 Quality Policy

Quality is regarded as of paramount importance at the Northern Ireland Blood Transfusion Service. This Quality Policy applies to all services provided by NIBTS

- Collection, processing, testing, storage and Issue of Blood Components
- Collection, processing, testing, storage and Issue of Umbilical Cord Blood Cells
- Procurement and Provision of Plasma Products
- Provision of Patient Testing Services – Blood Group Serology and virology screening (HIV, HbsAg, Syphilis and Rubella Immunity), for Antenatal Patients, and References Services to Hospital Blood Banks in N Ireland for Blood Group Serology and Platelet Serology.

This commitment is demonstrated by the development of a quality management system, which will ensure the provision of safe, efficacious and timely blood products and services for both patients and donors. This system will comply with all relevant legislation including Blood Safety and Quality Regulations, Human Tissue Quality and Safety Regulations, Environmental legislation, and CPA Accreditation standards.

The policy rests on the following principles:

- Our definition of quality is 'conformance with requirements'. We will carefully specify the requirements for our suppliers and our processes and will comply with the requirements of our users. Performance against these specifications will be monitored

- The training and education of staff shall be of a level to ensure that all staff recognise their responsibility to maintain and improve quality through awareness of this Manual and compliance with relevant procedures. Staff are committed to good professional practice.

- The health and welfare of staff and visitors.

- We will set quality objectives to maintain and improve quality through a planned system of quality management, which will cover every part of our activity. An essential part of this system is audit and review procedures.

This policy will be communicated to all staff and will be reviewed annually for suitability and effectiveness.
2.3 Quality Objectives / Planning

Within NIBTS departments and functions will set a wide range of Quality Objectives. The management review (see section 2.7) is undertaken on an annual basis and determines if the objectives have been successfully completed thus providing an opportunity for revision of objectives and plans and the functioning of the quality management system. An SOP: QA:101 – ‘Procedure for the Management of Evaluation and Continuous Improvement’ includes relevant detail.

2.4 Control of Documents

Documents are controlled through Q-Pulse and through this system management ensure that all critical documents are managed appropriately. Document types, which are controlled, include:

<table>
<thead>
<tr>
<th>Document Type</th>
<th>SOP Title</th>
<th>Document Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Standards</td>
<td>Control of External Documents used within NIBTS</td>
<td>SOP:QA:104</td>
</tr>
<tr>
<td>Specifically - Donor Selection Guidelines</td>
<td>Internal Circulation of National Guidelines for Blood Transfusion Services as issued by JPAC</td>
<td>SOP:QA:083</td>
</tr>
<tr>
<td>Policies</td>
<td>Preparation and Control of Policy Documents</td>
<td>SOP:QA:103</td>
</tr>
<tr>
<td>Procedures and Forms</td>
<td>Control of Standard Operating Procedures and forms related to SOPs</td>
<td>SOP:QA:026</td>
</tr>
<tr>
<td>User Requirement Specifications</td>
<td>Non IT Validation procedure</td>
<td>SOP:VL:001</td>
</tr>
<tr>
<td>Validation Documents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>Records Retention and Disposal Schedule</td>
<td>DHSSPS Good Management, Good Records</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laboratories and Quality Management and Retention of Laboratory Records</td>
<td>SOP:IG:004</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>External Storage</td>
<td>SOP:IG:003</td>
</tr>
</tbody>
</table>
Preparation, Revision, and Distribution of Documentation.

Documentation is based on SOPs, Computer User Documents, National Guidelines, Donor Records and records of test results, much of which are held on computer.

All departments contribute to the preparation of documents specific to that area. The relevant Heads of department or Senior Manager if necessary reviews all controlled documents for compliance with regulatory requirements. Authorised SOPs are issued on controlled paper.

The issue and withdrawal of SOPs is covered by a specific document. Included in this is detail on how the issue, review and withdrawal is controlled.

Where appropriate hard copy masters are stored by the Regulatory Affairs and Compliance Department.

A record/session slip is produced for each donor attendance (whole or cord blood)

The information contained in this record is:
- Identity of the donor including the donors record number
- Unique number assigned to a donation
- Date and place collected
- Any relevant medical information
- Record of any incident occurring during or after donation.
- Full or part pack

This information is entered into the PULSE computer system by donor records staff. Relevant medical information is referred to a medical officer, before entry to the computer.

A computerised record of all units processed is maintained by logging the units for processing. The record contains the unique donation reference number and the identity of products produced.

The pack type is linked to the lot number at goods inward inspection. Each donation is entered into the computer using a barcode scanner to wand the donation number and lot number.

The Quality Control Laboratory maintains records of regular product quality testing for 30 years. Results are reviewed on an ongoing basis with a formal document review monthly.

Records relating to all patient testing processes are retained. The Diagnostic Services System is the central computer system used to collate, retain and report patient testing information.

All IT systems are validated.

Other Documentation relating to product quality:

- Equipment Specifications
  Specifications for major items of equipment are prepared.

- Computer Program specifications
  Specifications are prepared and "signed off" with Savant by the NBS on behalf of the NIBTS.
A record of all goods received by the NIBTS is maintained.

- Purchase Order Request
- Purchase orders are required for all non-stock items.

- Audit Report Forms
- Quality non-compliances and corrective actions are recorded.

- Validation Records
- Where appropriate the validation of process, equipment and software is recorded.

NIBTS have implemented a procedure to control the review, approval and issue of documentation, which includes:

- Quality Manual
- Procedures
- Forms
- Risk Assessment
- Validation
- Specifications
- Technical Agreements
- Documentation relating to Product Quality

2.4.1 External Documents are also controlled and include:

Donor Selection Guidelines, Guidelines for Blood Transfusion Services in the UK are controlled via specific SOPs as noted at 2.4.

2.4.2 Control of applicable legislation and other requirements

See 2.4.1

2.5 Change Control

The NIBTS Change Control Policy POL:QP:012 outlines the overall approach in NIBTS. Any changes to our process, specifications or validation status is controlled and authorised by the Change Control Procedure. – SOP:QA 081 (See 5.3 for more detail)

2.6 Control of Records

The requirements for Control of Records are set out in a number of documents. The Retention and Disposal Schedule is a key document in this process. This and other relevant documents are detailed below. See also details in section 2.4 Specific details will be included as appropriate in operational SOPs.

2.7 Management Review

A wide range of review processes exist. Relevant meetings include the review of key quality issues including incident management, document control, change management, internal audit and External Quality Assessment scheme performance along with other specific quality objectives. The Quality Improvement Review meeting reviews specifically Quality Management system compliance on a monthly basis against a Quality Metrics
Site Quality (Master File) Manual

Report. An Incident Management Group and the Change Control Group support this meeting. NIBTS will carry out Annual Management Reviews in relation to specific areas e.g. Diagnostic Testing as required under CPA.

These regular quality system is reviews ensure that the quality system is revised to improve it when such opportunities are identified.
(See POL:QP:001 – ‘Quality Management Review Policy’)

A team of relevant staff will complete each review. They will review the quality system at least annually to ensure its continuing suitability, adequacy and effectiveness in satisfying the requirements of, relevant legislation/standards e.g. BQSR/CPA/HTA and contractual requirements. Records of Management Reviews will be maintained.

The Agenda for the review may vary depending on the regulations/standards involved. The requirements for such reviews can be pre-determined in the standards e.g. CPA requires topics be included in the Agenda

Agenda :
1. Minutes of previous Annual Quality Management Review meeting
2. Action list from previous Annual Quality Management Review meeting
3. Reports from managerial and supervisory personnel
4. Assessment of user satisfaction and complaints (H2)
5. Internal audit of quality management system (H5)
   Internal audit of examination processes (H4) -
6. External quality assessment reports (H5) - Status of preventive, corrective and improvement actions (H6) -
7. Quality indicators that monitor the laboratory’s contribution to patient care
8. Major changes in organisation and management, resource (including staffing) or process -
9. Follow up of previous management reviews covered under item 2,

Other headings, which may be used, include:
- Follow up actions from previous meeting.
- Review of Quality Policy.
- Supplier performance including review of Approved Supplier List.
- Review of external quality assessment reports.
- Annual Product Review including product release issues.
- Change Control.
- Results of Internal Audits.
- Review of Incidents, nonconformities, corrective & preventive actions.
- Review of any complaints and recalls.
- Regulatory review including any changes.
- Changes to the documented Quality Management System.
- Changes to the NIBTA business.
- Training Needs.
- Improvement Recommendations.
2.8 Validation

Validation and Calibration

All critical processes are validated in accordance with agreed procedures, key procedures in this are:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non – IT Validation Procedure</td>
<td>VL:001</td>
</tr>
<tr>
<td>Preparing a Mapping Report</td>
<td>VL:023</td>
</tr>
<tr>
<td>The NIBTS Validation Process for PULSE</td>
<td>QI:010</td>
</tr>
<tr>
<td>NIBTS Acceptance Procedure for PULSE</td>
<td>QI:014</td>
</tr>
<tr>
<td>NIBTS Acceptance Procedure for Generic Software</td>
<td>QI:015</td>
</tr>
</tbody>
</table>

All new equipment is validated.

All critical equipment including temperature-controlled equipment (Storage) is calibrated as part of planned preventive maintenance.

Computer software critical with regard to production is tested and validated. The process for PULSE involves testing by the supplier (Savant Enterprises Ltd), acceptance testing by the National Blood Service and where it is deemed necessary further on site testing at the NIBTS. The NIBTS second staff to take part in the NBS acceptance tests. The NIBTS acceptance process involves a review of the NBS Acceptance test scripts and results.

Regular checks are performed on measuring equipment e.g. scales, Hemocues according to written procedures.
3 Resource Management

NIBTS will ensure that appropriate resources are in place to deliver all services they provide to the necessary quality and to meet all regulatory requirements in the completion of this. Resources will include Premises, Equipment, Consumables and Staffing.

3.1 Organisation Charts

See Appendix 1 this includes a table identifying staff holding key posts/roles in NIBTS. It should be noted that the organisational charts set out managerial and scientific accountability arrangements.

3.2 Responsibilities & Authorities

Below are identified key roles within NIBTS relevant to licensing and accreditation requirements. Appropriate CVs for the individuals appointed to these Roles are included in the relevant licensing or accreditation applications.

NIBTS have documented key responsibilities and authorities and the interrelation of personnel who manage, perform and verify all work having an effect on quality. These responsibilities are not intended to be exhaustive but to assign responsibility for fundamental quality related activities.

The CEO will ensure clarity of responsibilities and will communicate these to all persons involved in the organisation.

3.2.1 Chief Executive

The post holder is the Accounting Officer, working through a management team to deliver:

1. Provision of all blood and therapeutic blood products for Northern Ireland.
2. Collection of blood (routine and apheresis), donor testing programme, blood processing and distributing of blood products.
3. Antenatal testing service.
4. Specialised reference laboratory service.
5. Bone marrow donor registry and umbilical cord blood bank.
6. Consultancy and training to all hospitals in Northern Ireland.

Accountabilities

1. Responsible for all aspects of operational management of NIBTS.
2. Responsible for the provision of adequate blood supplies to the HPSS in Northern Ireland to relevant standards.
3. Responsible for the development and delivery of the NIBTS strategic plan and annual business plan for approval by the Board.
4. Responsible for the maintenance and development of financial systems consistent with public accountability and corporate governance.
5. Responsible for the financial security of the organisation through contracts with the Regional Board and Trust.
6. Responsible for ensuring NIBTS achieves compliance with all relevant licensing organisations (BSQR/HTA/CPA etc).
7. Responsible for the management of all staff employed in NIBTS.
3.2.2 Medical Director

The Medical Director at NIBTS is responsible for all medical and scientific aspects of the Service. This includes, but is not limited to, blood collection services and donor testing, patient testing systems and the medical education programme. In addition they are responsible for medical contribution to regulatory compliance with the relevant inspecting bodies (HTA /CPA /MHRA).

The Medical Director is a member of the UK Forum, together with the CEO, and sits on Joint UKBTS /NIBSC Professional Advisory Committee (JPAC).

3.2.3 Quality Manager

The post holder will be responsible for the overall strategic development of Quality Systems in the Northern Ireland Blood Transfusion Service and works closely with the Regulatory Affairs and Compliance Manager to ensure that these systems meet the necessary regulatory standards (BSQR/HTA/MHRA/CPA) and others considered relevant to NIBTS. This will include the management of the relevant Quality Control laboratories. The post holder will be responsible for the overall development and implementation of appropriate Risk Management and Emergency Planning systems including Service Continuity Planning. The post holder will have overall responsibility for Information Governance within NIBTS ensuring that systems meet the requirements of relevant legislation including the Data Protection Act 1998, The Freedom of Information Act 2000 and DHSSPS guidance on these and Records Management.

3.2.4 Regulatory Affairs and Compliance Manager

The post holder will be responsible for the management of key aspects of the Quality System as detailed in 2.1. The scope of responsibility for this post is specifically designed to ensure the post holder can fulfil the role of Responsible Person under the BSQR. The post holder works closely with the Quality Manager to ensure quality systems comply with the BSQR and all other relevant standards applicable to NIBTS.

3.2.5 Laboratory Manager

The post holder will be responsible for all operational activities associated with the delivery of bio-medical services within the laboratories of the Northern Ireland Blood Transfusion Service (NIBTS), including the timely provision of blood and services to all hospitals within the province. Through professional leadership and effective management of staff, the post holder will ensure compliance with the quality policy of the Service and meet the relevant regulatory standards (BSQR/HTA/MHRA/CPA). The post holder will effectively manage change brought about by Department of Health initiatives, United Kingdom legislation and European Union directives in the Blood Service. Management of risk and service continuity planning are integral to the post. The post holder will assume the role of Laboratory Health & Safety Officer and implement laboratory safety measures in keeping with the Agency’s Health & Safety Policy and with external regulatory requirements.
3.2.6 Regulatory Roles - Responsible Person (BSQR) / Responsible Person (Wholesale Distribution) / Designated Individual and CPA Clinical Lead

Responsible Person
The Responsible Person will ensure the implementation and maintenance of appropriate systems to meet the following criteria as required by BSQR

The Blood Establishment
- Uses regularly trained and qualified personnel working with a Quality System (based on GMP), which includes responsibility for stores, warehousing, purchasing and estate.
- Uses validated processes for collection, testing, processing, storage and distribution.
- Supported by documented processes.
- Reports Serious Adverse Events and Serious Adverse reactions.
- Is able to reliably recall blood and blood components.

Selection of Donors and Collection
- Tell potential donors about the donation process, consequences, and data protection.
- Establish the audit trail by uniquely identifying the donor and donation, obtain medical history and obtain consent to donate.
- Ensure there is a process for donor selection that confirms fitness to donate by checking medical history for specific requirements (incorporated as part of Donor Selection Guidelines which includes more requirements)
- Check history before donation using suitable trained personnel, assess donor eligibility
- Endeavour to obtain voluntary donations by provision of information and marketing.

Testing, Processing, Storage and Distribution
- Following safe collection test each donation for all mandatory tests as specified in BSQR and specific extra tests e.g. Malaria
- Ensure the products are safely stored, transported and distributed.
- Ensure the products comply with specific requirements for content, potency and efficacy

Records
- Keeps contemporaneous records
- Manage data securely
- Keeps metrics round collection and distribution, Transfusion transmitted infection information. The donor history, consent and eligibility
- Keep an audit trail for tracing donations, but disclose information only as described to donors or if anonymised. Data must be kept secure.
- Data can be provided to a court of law or an inspector, for the purpose of linking a donation from a donor to a recipient. This inspector will keep information confidential; it can be shared providing it does not breach the information given to donors.

Labelling
- Label blood and blood components as described.
Responsible Person (Wholesale Distribution)
It is the duty of the Responsible Person to ensure that
- Wholesale distribution activities are undertaken in compliance with the relevant provisions of the Medicines Act 1968 as amended and the Medicines for Human Use Regulations 1994 as amended.
- Good Distribution Practice as described in the Guidelines for Pharmaceutical Manufacturers and Distributors are in place and being applied.
- Products are obtained from Bone fide suppliers
- Are only supplied too appropriate persons
- Systems to assure traceability and recall are in place

Designated Individual
It is the duty of the Designated Individual for Belfast Cord Blood Bank to ensure that the Human Tissue (Quality and Safety for Human Application) regulations 2007 are complied with and that all conditions of licensing by the Human Tissue Authority (HTA) are fulfilled. This includes, but is not limited to, ensuring that suitable procedures and policies are in place for all operations, premises and facilities are fit for purpose, a suitable programme of Quality Management is in place, and there is full traceability of all tissues and cells from donor to recipient.
An annual activity return must be submitted by the DI and they are also responsible for reporting all Serious Adverse Events and Reactions (SAEARS) to the regulator.

CPA Clinical Lead
NIBTS will identify a Clinical Lead to fulfil the responsibilities set out the CPA Standards at B1. This individual has executive responsibility for the services provided including the clinical, scientific, professional, consultative, advisory, organisational, administrative, and educational activities related to the services provided. These duties and responsibilities may be delegated.

3.3 Organisation and Responsibilities within NIBTS –
See 3.1, 3.2 and Appendix1

3.4 Provision of Resources

3.4.1 Personnel Management
Policies and procedures are available for all aspects of personnel management. Where procedures are not available centrally they are produced and updated by the NIBTS HR and Corporate Services department. NIBTS has indicated a Strategic Direction for Human Resources in a Human Resources Strategy – STG:HRS:001.

3.4.2 Staff Orientation and Induction
NIBTS has a comprehensive orientation and induction programme for all new members of staff. All staff attend the NIBTS Corporate Induction Session. NIBTS have an induction template, which is applied to all staff and includes a range of Mandatory training requirements. A specific requirement within the induction process is early attendance at GMP awareness training. The induction process is described in SOP:PE:005 – ‘Induction of a New Member of Staff to NIBTS’.
3.5 **Human Resources/Personnel**

### 3.5.1 Commitment and Planning

NIBTS are committed to ensuring appropriate numbers of suitable qualified and trained staff. Staffing requirements are regularly reviewed and with change control processes are assessed. The approximate current staffing resources are detailed below:

<table>
<thead>
<tr>
<th>Department</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor Services</td>
<td>90</td>
</tr>
<tr>
<td>Finance/IM&amp;T</td>
<td>6</td>
</tr>
<tr>
<td>HR &amp; Corporate Services</td>
<td>20</td>
</tr>
<tr>
<td>Laboratories</td>
<td>60</td>
</tr>
<tr>
<td>Medical</td>
<td>6</td>
</tr>
<tr>
<td>Quality</td>
<td>12</td>
</tr>
<tr>
<td>Regulatory Affairs and Compliance</td>
<td>8</td>
</tr>
</tbody>
</table>

See also Appendix 1

Where necessary specific details are included in relevant regulatory and accreditation application forms.

### 3.5.2 GxP Training (GMP/GLP)

NIBTS is committed to ensuring appropriate training for all staff. It has documented that commitment and this is set out in the Corporate Training Policy POL:PP:031 and departmental training SOPs. As noted at 3.4.2 NIBTS have a special commitment towards GxP Training. This arises from the range of regulatory and accreditation standards with which it must comply. Key elements would include:

- Good Manufacturing Practice specifically detailed by SOP:GL:008 – “GMP Training Procedure”
- Good Laboratory Practice
- Good Distribution Practice
- Good Documentation Practice

Staff are required to undertake GxP Awareness Training as part of their Induction Process, ideally within 10 working days of commencing employment.

GxP is embedded in its approach to all its procedural based training.

The NIBTS Quality department will provide a regular programme of GxP update training on an annual basis, which will be mandatory for all staff.

All training will be recorded.

Further Training Needs are identified by various means:

- Department/Section Heads in the course of the normal management process will identify requirements relating to specific employees so that they can function properly (e.g. training on SOPs)
Employees are encouraged to seek training as an element of their own career development commitments.

Staff Development Reviews

Normal job training takes place in the work area under the guidance of appropriate competent staff. Where specialised training is required, in house courses may be developed or trainees may attend courses off site.

NIBTS is under significant regulation based on GMP compliance. For this reason there will be particular focus on GxP training and staff will be required to attend annual GxP updates.

Retraining needs may be identified by staff rotation; incident reports or audit deficiencies noted

Training Records for all staff are maintained.

3.5.3 Competence, Awareness, Training and Education

A training and education programme exists for all staff and where appropriate is in accordance with the guidelines of the relevant Professional & Registration Bodies. Staff are required to maintain appropriate registration. This is monitored by professional managers in keeping with policy PP:034 Policy and Procedure for the Maintenance of Professional Registration which focuses on statutory registration for professionals.

Consultant medical staff are required to successfully participate in the CPD programme of the Royal College of Pathologists or other Royal College (e.g. Royal College of Physicians) Training of junior medical staff is conducted under the auspices of the relevant Council for Postgraduate Medical Education and fulfils the requirements of the Postgraduate Medical Education and Training Board (PMETB).

Training for Clinical Scientists is under the auspices of the Association of Clinical Scientists (ACS) and devolved to the relevant appropriate professional bodies. Health Professions Council (HPC) registered Clinical Scientists participate in the relevant CPD scheme under the auspices of the Royal College of Pathologists.

HPC registered Biomedical Scientists are encouraged to participate in the CPD scheme organised by the Institute of Biomedical Scientists and/or British Blood Transfusion Society. Pre registration Trainee Biomedical Scientists are trained in relation to the competencies, skills and knowledge based on IBMS Standards. Registration examinations are conducted in accordance with IBMS guidelines and regulations. NIBTS is approved by the Institute of Biomedical Science as a training laboratory for pre-registration Biomedical Scientists.

Training for Biomedical Scientists in NIBTS is organised through the Laboratory Manager with support from the Laboratory Training Officer. A Training and Audit sub-group of the Clinical Governance and Risk Management Group review training processes applied within NIBTS.

The HR and Corporate Services department co-ordinate corporate training e.g. Health and Safety. A Laboratory Training Officer has been appointed.

Nursing staff are required to successfully participate in the CPD programme as required by the Nursing & Midwifery Council.
Within NIBTS, nurses are competency assessed annually in relation to the skills and knowledge required by UKBTS/NIBSC Donor Selection Guidelines.

Other Staff
Other staff, including other professionals are encouraged to undertake any training, which will further develop them. Where appropriate NIBTS will support activities undertaken outwith NIBTS in keeping with NIBTS Post Entry Training Guidelines SOP:PE:003.

Department/Section Heads in the course of the normal management process will identify requirements relating to specific employees so that they can function properly (e.g. training on SOPs)

3.5.4 Job Descriptions and Contracts

Each member of staff has a job description and a contract of employment issued by the Belfast Trust’s Human Resources Department. Job Description are presented on a standard format FORM:DD:836.

3.5.5 Training/Staff Records

Relevant Managers, NIBTS HR department and the Belfast Trust HR department hold confidential staff records in a secure environment.

Records of attendance at relevant training courses and lectures with expected renewal dates are also held.

Staff annual leave is recorded on a daily basis. Staff sickness is recorded at both departmental and Trust levels and is reviewed regularly.

There are a variety of internal systems to record accidents and incidents. Health and Safety Incidents are recorded via IR1 forms.

3.5.6 Staff Reviews/Appraisals

All staff members must participate in an annual Staff Development Reviews review that includes consideration of:

a) the stated quality objectives and plans for their area and links to NIBTS corporate plans
b) the current job content and KSF outline
c) documentation of training needs and agreed personal objectives with the appraiser
d) evidence of individual action if personal objectives are not met
e) evidence that management has recognised the agreed development needs of individual staff members

All staff performing annual reviews are trained in the process and all those staff participating have had a full explanation of the process. Records are kept of all staff reviews in confidential staff files. Review dates are set for subsequent meetings. The approach to these within NIBTS is set out in policy document POL:PP:021 – ‘Knowledge and Skills Framework Policy’.
3.6 Infrastructure, Premises and Work Environment

3.6.1 Premises and Environment

Site Description for facilities at NIBTS, Belfast City Hospital

The site occupies an area of two acres located adjacent to the Belfast City Hospital approximately 2 miles from Belfast city centre and 0.5 mile from the motorway network for the province. The surrounding area is predominantly residential.

The facility is purpose built being occupied as of July 1995. The building also provides accommodation for the Regional Tissue Typing Laboratory, Patient Testing Services as provided by the Northern Ireland Blood Transfusion Service and a Cord Blood Bank accredited by the HTA.

The building extends to approx. 4,500 square metres of accommodation. The buildings are of reinforced concrete with a brick exterior and a tiled roof.

The main laboratory areas are: (approximate area)

- Blood Collection Unit, 200 square metres
- Blood Components Laboratory (Primary Processing), 200 square metres
- Microbiology Laboratory, 150 square metres
- Donor Grouping, 50 square metres
- Quality Control Laboratories including Bacteriology, 120 square metres
  - Antenatal Laboratory, 180 square metres
  - Blood Group Reference Laboratory, 100 square metres

The Blood Collection Unit in the city centre is located on the fifth floor at: College Street, Belfast. This site extends to approximately 250 square metres.

Details

- The building adjacent to the Belfast City Hospital is a purpose built facility. The NIBTS has been operational in this facility since the 24th July 1995. The building also provides accommodation for the Regional Tissue Typing Laboratory, Patient Testing Services as provided by the NIBTS and the Belfast Cord Blood Bank.

- Access to the building is controlled by way of a swipe card access system. This facilitates multiple levels of access to specific areas within the building.

- The building in total extends to approx. 4,500 square metres. The facilities for storage and distribution represent approx. 200 square metres. All storage areas are secure, all of these being on the ground floor. All appropriate temperature conditions are maintained and monitored.
The production, storage and distribution areas have been designed to facilitate a flow from receipt of whole blood through processing into appropriate storage for each product type to at issue status, again in controlled secure environments. Continuous and alarmed temperature monitoring is provided.

Areas are designated for the blood ‘in process’, ‘in quarantine’ ‘pending routine clearance’ and ‘at issue’. Extra security has been allocated to areas for the storage of non-conforming products, including those rejected, recalled or returned unfit for use. A strict inventory exists.

Areas are designated for the secure storage of all materials including such items as blood packs, microbiological screening kits and serological reagents used for testing blood. Microbiological Screening kits and serological reagents are stored either as not validated or validated for use in separated areas.

Areas for the receipt of materials and blood are covered to protect such deliveries from the elements.

Secure areas exist for the storage of labels for use on blood products.

The areas for the issue of products are secure. They facilitate the receipt of requests, picking and preparation of consignments. These consignments are packaged in suitable containers, which maintain the storage temperature for known time periods. Access for the collection of these consignments is controlled.

An Irradiator for the irradiation of blood components is situated adjacent to the blood bank area in appropriately controlled room.

Plans for each level of the building are maintained

Construction and Finishes

The laboratory facilities which house processing and testing facilities occupy a portion of the ground and first floor of the NIBTS building at the Belfast City Hospital Site. The building is purpose built of reinforced concrete and brick under tiled roof.

Internal walls are plastered and finished with an impervious coating. Floors are covered with a vinyl material, which is anti-slip, with finished up skirting and welded joints.

Ventilation

Space Heating Installation

General Office areas, corridors, etc are heated by radiators served by a dual pipe compensated LTHW system. Other areas such as Laboratories have a dual heating system with perimeter panels/radiators off-setting the fabric load, a Plenum heating system to offset the air load and satisfy the ventilation requirements.
LPHW pipework is medium grade steel, insulated, distributed through the building via builder’s vertical shafts, suspended ceiling voids and within perimeter pipe casings.

Ventilation/Air Conditioning Installation

Ventilation/Air conditioning is included in the various areas to provide positive/negative/neutral pressures all as dictated in Room Data Sheets and Statutory Requirements.

The three “wings” of the building each have a central air handling unit, double skinned, located in the rooftop plant room, comprising the following components:-

Pre-filter, energy recovery run around coil, bag filter EU3, chilled water cooling coil, LPHW heating coil, inverter controlled supply fan section with drive assembly outside air stream, isothermal humidifier and Melinex lined attenuator.

Associated with the supply air handling unit is an exhaust air handling unit comprising the following components:-

Attenuator section, energy recover run around coil and inverter controlled exhaust fan section.

Supply air is distributed from each of the AHU’s via low velocity insulated ductwork from the plant room down the vertical service shaft with branch mains into the space served on each level. Within each “Room Zone” a variable air volume terminal controls the air volume, temperature, etc. to satisfy the room load.

Exhaust air is returned to the plant room in low velocity insulated ductwork in the reverse route. Heated extracted air passes over the run around coil before being exhausted. The energy recovered from the extracted air is transferred to the supply air handling plant, when required.

Computer Rooms are conditioned by floor mounted packaged close control air conditioning units with matched outdoor condensing units. As the Computer Room is located on Level 3, the condensing units have been positioned in the Plant Area to facilitate maintenance outside the Computer Room.

To maintain conditions within the ‘Clean Rooms’ separate air handling units have been provided.

The class of Clean Rooms specified may be referred to the classification as established by the British Standard Institute to BS 5295 : Parts 0 to 4, 1989.

All air handling unit components, condensate drainage traps, etc are in accordance with the Legionellae Code of Practice.

The Clean Room air handling plant comprises the following components, mixing box, pre-filter, LPHW, frost coil, bag filter, chilled water cooling coil, LPHW heating coil, 2-speed supply fan section with inlet guide vanes, isothermal humidifier, attenuator, HEPA filter and return air fan. A proportion of supply air is re-circulated with the required air volume continuously introduced.

The toilet facilities are provided with a low velocity insulated ducted extract system to a twin in-line exhaust fan unit with an auto-changeover facility in the event of fan failure.
Make-up air is introduced via wall mounted transfer grilles fitted.

Fume cupboards/safety cabinets are provided as required. The uPVC fume exhaust ductwork, fire protected, is taken to the rooftop plant room via the vertical builder’s shafts. Fume extract fans are multi-vane centrifugal fans, belt driven, discharging vertically into a uPVC stack taken 3.0 m approximately above the roof apex. The fans are positioned externally with all ducting within the building being under negative pressure to prevent leakage of fumes into the building if a duct seal should fail.

Chilled Water Installation
The chilled water cooling system is provided to meet the cooling requirements of the ventilation/air conditioning/Clean Room air handling plant. The units are duplicate, duty/standby, air cooled liquid chillers producing chilled water at 6 °C.

The units are mounted on a concrete support platform in the “well” on the main roof, accessible from the plant room.

Chilled water is circulated through the system by a twin pump set and distribution pipework, heavy grade steel.

The liquid chillers are protected by a line duplex filter and frost protection of the system is provided by a 25% charge of “NAPGEL C2230” anti-freeze.

Other aspects

High Potency hazardous materials are not dispensed or manufactured

Virology testing of samples from Blood Donors is undertaken in a dedicated area where specific protective clothing is required.

The site is supplied with water from the local mains system.

- Mains water is used to produce purified water by a system which combines filtration and deionisation. This water is used in the preparation of solutions and in the rinse cycle of tests.

- Water is not used in the preparation of blood components

The routine maintenance of the premises is carried out by the Belfast Trust Estates department.

Maintenance is supplemented by service agreements with outside contractors (normally the installers or suppliers).

Records of work performed are maintained.
Site Quality (Master File) Manual

3.6.2 Facilities for Staff

All premises have staff facilities that are readily accessible and include:

- Sufficient toilet accommodation
- Shower facilities where required
- A rest area
- Basic catering facilities and access to a supply of drinking water
- A changing area where required and secure storage for personal effects
- Storage for protective clothing
- Safe and secure working arrangements
- When necessary e.g. on-call, there shall be overnight accommodation that is conveniently sited and secure.

3.6.3 Facilities for Patients

Patients do not attend NIBTS. Facilities for specimen collection and examination of patients are mainly located in the Outpatients Departments of the HSC Trusts including Belfast. Haematology and Oncology patients are seen on Bridgewater Suite (opened 2003) on the BCHT site which is adjacent to the Haematology Laboratory.

Paediatric Haematology patients are bled in a dedicated room beside the Paediatric Haematology Laboratory in the RBHSC.

A number of patient consultations and Sweat tests are carried out within the Kelvin Building on the RGHT site.

Immunology patients are seen at the Immunology Day Centre situated at the Royal Hospitals site.

Other HSC Trusts provide similar arrangements.

These facilities include as appropriate:

- A waiting/reception area for clinic/ phlebotomy patients
- A phlebotomy area which offers privacy and recovery facilities
- Consulting rooms for clinics and patient examination
- Separate toilet facilities for patients

Access and facilities for disabled patients

3.6.4 Facilities for Storage

All premises provide sufficient storage space in accordance with national legislation, regulations and guidelines. There are separate storage facilities as required for:

- Process and quality records
- Clinical material - stored under appropriate conditions for an appropriate period of time.
- Blood, blood products, cord blood and pharmaceutical products – are stored in dedicated cold rooms/refrigerators/ freezers which are constantly monitored with respect to temperature using either electronic monitoring devices. Alarm systems are employed to warn staff in the event of temperature related problems.
- Hazardous substances
Drugs, and other therapeutics
- Reagents - are stored in dedicated cold rooms/refrigerators / freezers which are constantly monitored with respect to temperature using either electronic monitoring devices. Alarm systems are employed to warn staff in the event of temperature related problems
- Waste material for disposal

3.6.5 Health and Safety

The Chief Executive of NIBTS has overall responsibility for the health & safety of all staff, visitors and patients. NIBTS has created a Health & Safety Committee which has staff side and management side representatives. This committee promotes co-operation and consultation between the Agency and staff in instigating, developing and carrying out measures to ensure the health, safety and welfare of all staff, patients and visitors.

NIBTS Management Team also ensures there is a safe working environment in accordance with current legislation through the Facilities Manager, as NIBTS health and Safety Officer and the appointment of part-time Health & Safety Leads within departments.

Arrangements are describe in the “Health and Safety at Work – Policy and Organisational Arrangements Policy” document (Ref: POL:HP:001). This document is supported by a number of other policies and procedures.

Specifically within laboratories responsibility for Health and Safety is delegated through the Laboratory Manager to the Laboratory Training Officer (LTO). This aims to meet the requirements of the CPA for a dedicated individual within laboratories to act as the Laboratory Heath and Safety Officer. The LTO job description includes more detail on this role.

Health and Safety Policies and Manual exist with NIBTS are regularly reviewed and updated. These are made available to all staff.

Procedures exist for:
- Action in the event of a fire
- Action in the event of inoculation accident
- Recording and monitoring accidents and incidents
- COSHH/Risk Assessments
- Procedures for disinfection
- Decontamination of equipment
- Chemical Handling
- Storage and disposal of waste
- Specimen collection and handling, transportation, reception and referral to other laboratories
- Action in the event of a major spillage of dangerous clinical material
- Waste Management Policy

All staff members are made aware of their responsibilities relating to health & safety and are mandated to attend a fire / safety lecture on a regular basis. Centralised training records exist.

All accidents and adverse incidents are recorded using the IR1 System. Such incidents are monitored and reports provided to the Health and Safety Committee and the Governance and Risk Management Committee on a regular basis.
All samples are handled according to a minimum of CL2. Personal protective equipment is provided.

Work areas are clean, uncluttered and well maintained. Evidence of good housekeeping procedures is demonstrated by good laboratory practice (GxP) records, instrument log books, analyser maintenance records and reagent records.

Laboratory containment facilities conform to the requirements of COSHH and the Advisory Committee on Dangerous Pathogens (ACDP) Guidelines as appropriate to the testing being performed.

Safety notices are displayed throughout NIBTS for the benefit of all staff and visitors to the departments.

3.6.6 Health Requirements of Personnel engaged in Production

All staff are required to report when they are unwell. There is a facility to refer employees to Occupational Health Service if necessary.

Any prospective employees undergo pre-employment medical screening, including testing for HbsAg, by Occupational Health Service.

Where appropriate employees may be required to undergo specific health checks.

There is a standard routine for reporting sickness absence through the department/Section Head.

Employees are required to report to their Department/Section Head after sickness absence. In some cases it may be deemed necessary for employees to be positively cleared prior to return to work.

3.6.7 Personnel Hygiene requirements including clothing

All staff are aware of the need for hygiene for reasons of Health and Safety and Product Sterility. Appropriate measures are taken at all times to ensure that adequate hygiene is maintained.

Personal protective equipment will be provided as appropriate to all staff and should be worn in accordance with the “Personal Protective Equipment Policy” - POL:HP:012.
4 Process within NIBTS

4.1 Blood Collection

Each year over 60,000 people attend blood donation sessions in Northern Ireland, serviced by three mobile units, and fixed locations at NIBTS Headquarters and College Street Belfast. Units are staffed by a multidisciplinary team comprised of a doctor or nurse, donor session assistants, admin and session support assistants. Voluntary help is sometimes available to assist with the provision of refreshments for donors.

4.2 Blood Testing and Processing

Production Outline
The major manufacturing operation of the Northern Ireland Blood Transfusion Centre is the preparation of human cellular and plasma derived therapeutic blood products from individual donations collected either from as whole blood or by apheresis.

Processing of blood donations to produce blood components is undertaken. This involves centrifugation under controlled conditions and the transfer of components from one pack to another within a closed system, usually by use of automated blood processing machines.

All products produced, with the exception of granulocytes in the form of buffy coats are leucodepleted.

Labelling of finished products is computer controlled and utilises ‘demand’ printers

4.3 Quality Control

Quality Control Activities
Testing of samples from blood donations is undertaken a number of laboratories at NIBTS

Donor Grouping Laboratory - the donations are ABO and Rh. typed. In addition the donations are screened for any clinically significant atypical red cell antibodies.

Microbiology Laboratory - the donations are screened for mandatory microbiology markers as prescribed in the current BSQRs and UK BTS Guidelines

The Quality Control Laboratories are responsible for:-
- Product Quality Monitoring in accordance with BSQR and UKBTS Guidelines
- Bacterial Testing on Platelets
- Environmental Monitoring
- Goods Inward Inspection on a number of key consumables including blood packs and labels
- Monitoring of blood bag and apheresis equipment faults.

NOTE - In addition to the testing identified above NIBTS contract out testing.
Details of this can be found at page 8 of this document.
4.4 Release of Blood and Blood Components

Product Release is computer controlled and requires two valid grouping results together with negative results for all mandatory microbiology screens.

4.4.1 Deviations

Any deviations from agreed standards are logged as an incident which ensures appropriate reporting, investigation corrective and preventive actions take place. These are managed through the ‘Procedure for Reporting and Management of Quality Incidents’ – SOP: QA:070.

4.5 Storage and Distribution

4.5.1 Storage

See NIBTS Policy for “Storage and Transportation of Blood Components” - Ref: POL:LP:004

Storage facilities are provided as required to ensure that appropriate conditions, in line with regulations and manufacturers instructions, are maintained. This includes a range of ambient stores and strict temperature controlled storage areas/equipment. Specific provision in relation to blood and blood components include:

- A 36 cubic metre cold store held at 2-6°C equipped with over and under temperature alarms and a computer record of temperature is used to hold cellular products in quarantine.

- A 24 cubic metre cold store held at 2-6°C equipped with over and under temperature alarms and a computer record of temperature is used to hold cellular products at issue.

- A 36 cubic metre cold store held at 2-6°C equipped with over and under temperature alarms and a computer record of temperature is used to hold pharmaceutical products.

- Cold rooms and free standing freezers which operate at or below -30°C are provided to hold Frozen Plasma products as quarantine and issue.

- Platelets in quarantine and at issue are held in two separate temperature controlled cabinets that are sited in different rooms. Each cabinet is equipped with mixers and alarms for high and low temperatures and failure of mixers.

- All temperature critical storage is controlled monitored and alarmed.

4.5.2 Distribution

Routine deliveries of blood and blood products to user hospitals are made via NIBTS transport, Hospital transport, and taxis. All products are transported in containers validated to maintain the required storage conditions.
4.6 Contract Management

NIBTS utilise contracts to manage a number of services. These are managed through Procurement and Logistics as noted in 1.1 or locally by NIBTS in keeping with the procedure – “Service Level Agreements” - SOP:GL:005.

4.7 Procurement and Management of Equipment

4.7.1 Overview

NIBTS Management Team ensures that the equipment is sufficient and appropriate to provide the service required.

The HSC Procurement and Logistics Services (PaLS) has developed procedures to be followed for the procurement and replacement of equipment. PaLS provides expertise, knowledge and assistance to NIBTS for the procurement process. Laboratories may also have equipment on loan from manufacturers.

The document ‘Purchasing GxP Equipment’ SOP:GL:009 sets out the process to be used for the purchase of such equipment, implementation, and maintenance of all critical and quality impacting processes, equipment within NIBTS. It covers aspects including:

- Assessment and justification of need
- Selection criteria
- Acceptance and evaluation
- Training (if provided by manufacturers is part of the specification)
- Records of maintenance, service history, repair and calibration

Ensures procedures for:

- Decontamination of equipment
- Adverse incident and corrective action logging
- Record of instrument failure and subsequent corrective action
- Planned replacement and disposal of equipment

Ensures records of an inventory of equipment that includes:

- Manufacturers name
- Serial number
- Date of purchase or acquisition
- Record of contracted maintenance
- Record of equipment downtime
- Record of equipment downtime

Records of equipment electrical safety checks are held by the Estates Department of the Belfast HSC Trust. The date of the most recent check is clearly marked on the equipment.
4.7.2 Maintenance & Calibration

SOP: GL:006 Equipment Maintenance details how maintenance and calibration are managed. This includes the requirement for detailed checklists, which used by engineers to records maintenance and calibration activities and facilitate checking by relevant NIBTS staff. Individual Equipment files are developed for all GxP equipment. These hold all relevant records including equipment maintenance and calibration records, this is described in SOP GL:007

4.8 Management of Data and Information

Data and information are available to provide a service that meets the requirements of users.
PULSE and the Diagnostic Services System are central to this. The various servers and other applications used within NIBTS are maintained and managed by IT professionals.

A set of policies and procedures includes information on data handling within NIBTS and addresses such issues as:
- Security
- Access
- Confidentiality and Data Protection
- Back-up systems
- Storage, archive and retrieval
- Safe disposal

See also sections 2.4 and 2.6.

4.9 Management of Materials (Including Reagents)

NIBTS Management Team ensures the availability of reagents, calibration and quality control material required to provide a service that meets the needs and requirements of users.

A number of procedures control the following:
- Selection, purchasing and ordering
- Assessment of suppliers
- Receipt and verification of identity and condition
- Risk assessment through classification of hazard and exposure potential assignment of handling precautions when appropriate
- Safe disposal
- Materials in use are correctly identified with the date of receipt, lot numbers, first use and expiry.

4.10 Control of Purchasing (Suppliers)

The HSC Business Support Organisation provides Procurement and Logistics Services to NIBTS by way of a service level agreement. In addition NIBTS review suppliers by a range
of means including supplier audit. This is outlined in the procedure ‘Supplier Assessment’
procedure SOP:QA:077.

4.11 Identification & Traceability

4.11.1 Identification

All donors, patients, donations, samples, and components are uniquely identified when
entering into NIBTS systems.

Donors are allocated individual Donor Numbers and any donations donated are identified
with a unique ISBT Code 128 donations number (bar-coded) This number facilitates robust
tracking and linkage of all information, donor, product and sample testing to ensure that the
donor and donation are controlled appropriately. This donation number facilitates accurate
labelling, release and issue of all components.

Patients from which samples are received are allocated a unique patient number from
within the Diagnostic Services System. This and an individual sample number facilitate
linkages of patient and testing records to assure the release of accurate results/reports.

4.11.2 Traceability

It is essential that NIBTS have in place systems, which ensure traceability. For this reason
extensive records are made of the identity of consumables used. This may be on IT
systems or in hard copy depending on the process and consumables.

As noted in 4.11.1 unique numbers are allocated to all blood components and cord blood
donations. These unique numbers allow the tracing of all components etc from collection to
issue. NIBTS have in place procedures to ensure any issues arising in traceability are
addressed. A procedure exists to manage look back on donated blood.

4.12 CPA Requirements

4.12.1 Pre Examination Process

4.12.1.1 Information for Users and Patients

Information for users is contained in the ‘Prospectus and User Guide’ Ref:FORM:DD:892,
the information includes:

- Contact details of key members of staff.
- The locations of the laboratories.
- Services offered
- Times of opening of the laboratories.
- Details of the out of hours service.
- Instructions on the completion of the request form.
- Instructions for the transportation of samples, including any special handling
  requirements – See also the SOP ‘Transport of Samples to NIBTS’ –
  (Ref:SOP:HS:009).
- Availability of clinical advice and interpretation.
- Names and addresses of laboratories to which work is referred
• The repertoire of the laboratory including specimens required, sample volumes, special precautions and turnaround times.

• A list of those key factors which are known to affect the performance of the test or the interpretation of the results.

Time limits for requesting additional investigations

4.12.1.2 Request Form

NIBTS makes available to all its users, request forms that have been designed to include:

• Sufficient information to allow unique identity of the patient
• The source of the request
• Identification and the location of the requesting individual
• The date and time of specimen collection
• The type of specimen
• The investigations required
• Date and Time of receipt of samples by the laboratory
• Relevant Clinical Information
• Identification of Priority Status
• Location to which results are to be sent
• The laboratory accession number
• The risk status e.g. HG3 specimen
• Details of how these can be obtained are included in the NIBTS Prospectus and User Guide

4.12.1.3 Specimen Collection and Handling

NIBTS do not control the collection of samples. Those collecting samples are given advise in the NIBTS Prospectus and Users Guide and relevant National Guidelines are highlighted. These address the following issues.

• Checking the completion of the request form and confirming the identity of the patient.
• Checking that the specimen container is labelled correctly and in date for use
• Checking that the patient is appropriately prepared.
• Ensuring that the specimen collected correctly.
• Minimising the risk of interchange of samples and sub samples.
• Ensuring environmental and storage conditions are fulfilled
• Ensuring the safe disposal of all materials used in specimen collection.
• Ensuring that high risk specimens are identified and processed correctly, see SOP ‘The Handling of Specimens from Patients Suspected(or known) to be Infected with Hazard Group 3 Pathogens’ – Ref: SOP:HS:006.
• Ensuring that all spillages and breakages are dealt with correctly.
• Minimising the risk to ensure the safety of the specimen collector, carrier, the general public and the receiving laboratory.

Information on collection and handling of specimens is available to other users of the service via the NIBTS Prospectus and User Guide and local Trust Laboratory Handbooks.

4.12.1.4 Specimen Transportation
NIBTS are not responsible for the management of specimen transport to NIBTS. Model rules for specimen transportation have been drawn up in conjunction with safety advisers to ensure that risk is minimised. A NIBTS procedure has been written in fulfilment of this standard. This procedure includes:

- Ensuring the safety of the courier, the general public and receiving laboratory.
- Packaging, labelling and despatch.
- Protection of the specimens from deterioration.
- Reporting incidents during transportation that may affect the quality of the specimen or the safety of personnel.
- The procedures for the transport of specimens meet all regulatory requirements,
- see the SOPs ‘Transport of Samples to NIBTS’ (Ref. SOP:HS:009) and Health and Safety ‘Rules for Porters and Couriers’ (Ref. SOP:HS:008).

4.12.1.5 Specimen Reception

NIBTS have SOPs which detail how specimens are received into the systems. These procedures include information relating to the following:

- Linking of the request and specimen
- Recording of request form and specimen information.
- Recording the date and time of receipt of specimens.
- Handling urgent specimens - where appropriate.
- Ensuring staff safety.

The procedures in place for specimen rejection include:

- The criteria for rejection of specimens.
- The recording of rejection specimens.
- Notification of the user concerning rejected specimens.

4.12.1.6 Referral to other laboratories

Some specimens requiring particular tests may need referral to specialist laboratories. Information on all referral laboratories and their repertoire is available from individual laboratory SOPs. In general these laboratories should be accredited. Each department has a documented procedure for the referral of samples which includes information on the relevant laboratories and what tests are obtained where.

- evaluating and selecting referral laboratories and consultants in terms of competence to perform the requested examinations and ensuring that there are no conflicts of interest
- maintaining a record of all referral laboratories and the relevant repertoire [NOTE 1]
- maintaining a record of all specimens referred
- recording of dispatch dates
- monitoring the return of reports from the referral laboratory or referral consultant
- defining the respective responsibilities for the interpretation and reporting of referred examinations (see also G2.4)
periodically reviewing the arrangements with referral laboratories to ensure that requirements including terms of EQA performance and turnaround times continue to be met.

4.12.2 Examination Process

4.12.2.1 Selection and validation of examination procedures

All examination procedures are validated prior to introduction. Validation is achieved either by acceptance of manufacturers’ data or by ‘in-house’ validation. Validation takes into account the needs and requirements of users. Details of initial validation and any changes to methods are recorded and stored. Where a change in method significantly affects the results or their interpretation, information on these changes is provided to users prior to the introduction of the change.

4.12.2.2 Examination procedures

Laboratory procedures (SOPs) for the conduct of all examinations are prepared according to the criteria in documents. These procedures will normally include the following details of:

- clinical relevance / purpose of examination
- principle of examination
- specimen requirements and means of identification
- equipment and special supplies
- reagents, standard or calibrants and internal control materials
- calibration
- instructions for the performance of the examination
- limitations of the examination, including interferences, cross reactions and reportable intervals
- recording and calculation of results
- internal quality control procedures and criteria against which examination processes (measurement and observation) are judged
- reporting reference limits
- alert/critical values, where appropriate
- responsibilities of personnel in authorising, reporting, and monitoring reports
- hazards and safety precautions
- performance criteria.

All examination procedures are readily available within the relevant section of the laboratory. These procedures are subject to document control and are reviewed on a regular basis and may only be amended by authorised personnel.

4.12.2.3 Assuring the quality of examinations

In keeping with the ‘Internal Quality Control Policy’ – POL:QP:010 all departments have either specific procedures for the use if internal quality control materials or included this in specific testing SOPs. This covers the use of such controls and the acceptance of these for all examinations including:
Site Quality (Master File) Manual

- implementation of appropriate pre examination processes
- the provision of trained staff, appropriate premises and environmental conditions, equipment and materials, information systems, and the use of documented procedures
- the use of internal quality control
- the determination of uncertainty
- calibration of measuring systems
- verifying the comparability of results
- and participating in external quality assessment schemes
- records of date, source, and storage requirements of IQC material
- the process of validation of IQC material prior to routine use
- appropriate statistical procedures
- where applicable, acceptance criteria for results obtained on IQC material in use.
- ensuring that all IQC results are recorded, regularly evaluated and subsequent remedial and corrective actions taken recorded.

4.12.3 Post Examination Process

4.12.3.1 Reporting results

NIBTS Laboratories strive to produce results of examinations in reports that are correct, timely, unambiguous and clinically useful. NIBTS will also provide effective clinical advice and interpretation when requested by our users. Each laboratory will define procedures for reporting results.

4.12.3.2 The report

NIBTS issues reports of examinations on hard copy and/or provides secure remote access to its Diagnostic Services System from which users can view results and print reports. The reports are designed in consultation with users and conform to the requirements of the hospital and GP medical record systems. The reports are both clear and unambiguous and contain sufficient information to enable the user to interpret the results. The report where appropriate includes the following information:

- the laboratory name
- the unequivocal identification of the patient
- requester and/or address for delivery
- type of specimen, date and time of collection
- date of report
- results, including reasons if no examination is performed (E5)
- reference intervals as appropriate
- interpretive comments as appropriate
- highlighting of abnormal results and/or inclusion of critical limits
- status of report as appropriate, eg, copy, interim or supplementary
- where possible, the identification of person(s) verifying results and authorising the release of the report.
- Reports or letters issued following receipt of the results from referral laboratories shall additionally:
  - include a means of identifying the referral laboratory [NOTE 2]
  - include all the results
  - incorporate appropriate interpretive comments of the referral laboratory
Site Quality (Master File) Manual

- When examination results from a referral laboratory need to be transcribed by the referring laboratory there are instructions for verifying the correctness of transcription

4.12.3.3 The telephoned report

NIBTS have in place procedures for the release of results by telephone. This details:

- The circumstances in which reports may be given.
- The individuals who may give reports.
- The individuals who may receive reports.
- A method of mutual patient identification between reporter and receiver.
- A confirmation of correct transmission.
- The mechanism for recording the event.
- The maintenance of confidentiality.
- The process for sending a follow-up reports if required.

4.12.3.4 The amended report

Occasionally it is necessary to amend a report. Where this occurs the relevant criteria below will be considered:

- The criteria for issuing amended reports.
- The authorisation of staff able to amend reports.
- The identification to the user of amended reports.
- A process for recording the issue of amended reports.
- The reason for issuing an amended report.
- The instigation of preventative action, if required.
- A process for archiving amended reports.

4.12.3.5 Clinical advice and interpretation

Appropriate investigation and the interpretation of results and clinical advice are available to users 24 hours a day. The clinical advice and interpretative comments on results are authorised by appropriate consultant medical staff.

4.12.3.6 Control of Clinical Material

Through the SOP Retention and Storage of Patient and Donor samples – LS:003 and laboratory management ensure that all clinical material is appropriately identified, stored and disposed of.

4.13 HTA Requirements

References to HTA requirements are include in the Cross reference at Section 6.

5 Measurement / Analysis / Improvement

5.1 Measurement, Analysis and Improvement

Crucial to our Quality System are our Measurement, Analysis and Improvement Processes that ensure:

- Conformity of our products and services
- Conformity of our Quality Management System
- Maintaining the effectiveness of our Management System
- We meet contractual and regulatory requirements
- We monitor, identify and continually improve our system, processes and respond to customer feedback.
- Monitoring and Measurement
Quality Improvement is managed by a number of procedures covering Incidents, Audit outcomes, User Feedback and involves the identification of issues, remedial action, and corrective/preventive action.


5.2 Customer Complaints/Feedback

Customer Complaints

Customers Complaints are managed by way of the Incident Reporting and Management Procedure – (Ref: SOP:QA:070). All incidents are investigated and reported. Included in reports are corrective and preventive actions. If necessary these reports are discussed at formal meetings in the relevant departments. A summary of incidents is reviewed at the Monthly Quality improvement Review Meeting.

Donor Complaints are managed by way of a specific procedure SOP:BD:017, ‘Procedure for Processing Complaints and Other Contacts’. This is consistent with HSC Guidance - Complaints in HSC – Standards & Guidelines (Apr 09)

HSC Complaints Procedure Directions (NI)

User Satisfaction and Feedback

A procedure exists for obtaining and monitoring User satisfaction and comments is in place SOP:QA:095 – ‘Procedure for the Management of Clinical User Surveys’. This includes both the use of questionnaires and face to face meetings. Outcomes are acted upon. Performance target information is available.

5.3 Change Control

The Change Control procedure - SOP:QA:081 describes how changes are managed in NIBTS. Change control is a fundamental requirement of any Quality Management System (QMS). The NIBTS QMS is designed to meet a range of regulatory and quality standards and of specific relevance are the Blood Safety and Quality Regulations 2005/50 and the Human Tissue Act. Central to these regulations is compliance with the principles of Good Manufacturing Practice (GMP) which requires the use of robust change control procedures. Planned changes are subjected to effective scrutiny by all affected parts of the organisation such that the full implications related to changes are documented and that changes are then subsequently implemented in a compliant manner. In addition to SOP:QA:081 a number of other procedures address change control. These include document control and validation project change management.

SOP:QA:081 is applicable to:

- Any planned change to any activity that affects NIBTS collection, processing, testing, storage, distribution, service provision and IT processes.
- Change of raw materials/packaging/labelling.
- Software upgrades which affect GMP processes/systems.
- Changes affecting GMP systems that require qualification/validation.
- Temporary planned deviations from currently approved procedures.
- Changes to NIBTS facilities including repairs to GMP areas.

The procedure does not cover:

Changes in equipment which are considered “like for like”. A “like for like” change is defined as a replacement of a serviceable part that is identical in construction and source and where that replacement does not require revalidation.

Changes to controlled documents, including SOPs, which only affects a single document and do not require significant re-training. Such changes are managed by the document control system.
Changes to controlled documents, including SOPs, which do not affect GMP processes/systems. Such changes are managed by the document control system.

Changes to systems that have no impact on GMP processes/systems. Such changes must be controlled via the appropriate alternative SOPs and/or documentation within the department concerned.

OBJECTIVES

The principal objectives of Change Management are as follows:

- To ensure that any planned changes or modifications to processes, procedures, policies, equipment, facilities or computer hardware/software, which may impact on the quality of the product or service provided by NIBTS, are assessed by the relevant personnel within the organisation such that comprehensive action plans are developed.
- To plan the implementation of the change, so that minimum of disruption is caused.
- To ensure that all the requirements for validation prior to implementation have been considered, addressed and completed.
- To ensure that all training requirements have been identified and training carried out.
- To ensure that all documentation required has been identified and is in place before the change is implemented. The minimum documentation required will vary depending on the nature of the change. Examples of documentation required to support a change would include:
  - Completed validation reports
  - Completed risk analysis
  - Completed commissioning reports
  - Summarised lab test data
  - New revised SOP
  - Evidence of training
- To ensure that all changes have a documented, traceable record available.
- To ensure that effective follow-up studies are carried out to demonstrate that the change has been implemented as anticipated.

5.4 Recall

There are defined recall procedures in the form of SOP:QA:002: – ‘Blood Component Recall’ and SOP:QA:102 ‘Procedure for the Recall of Pharmaceutical Products’. These procedures detail the sequence of actions to be followed including identification of the location of recalled products and notification to customers. Recall is co-ordinated by the Quality and Regulatory Affairs and Compliance Departments appropriately.

5.5 Internal Auditing

NIBTS will develop an internal audit plan, which will meet the requirements of various regulatory requirements and standards as appropriate. All processes will be subject to internal audit; this will include both the Quality Management System and operations.

Internal audit provides evidence that the quality management system has been effectively established, implemented and maintained. Systems of internal audit of the QMS have been established and laboratory audits are conducted according to a preset schedule and against agreed criteria. Individuals from a range of professions and levels, with appropriate training perform audits and if possible by those who are independent of the work being audited. The results of internal audit of the QMS are regularly evaluated and any decisions taken to alter/improve the QMS are documented and are subject to monitoring and review through the Change Control Procedure if appropriate.

Audits of operational processes will be such that they require the requirements of the CPA covering pre-examination, examination and post examination criteria.

The NIBTS Internal Audit Process is described in SOP:QA:003.
5.6 External Quality Assessments

All departments within NIBTS laboratories participate fully in approved external quality assessment schemes appropriate to the examinations and interpretations provided. Performance in EQA is reviewed at relevant operational meetings and communicated to all staff. Current external QA reports are displayed in the relevant Departments and past reports are available for review. An overview of performance in external quality assessment schemes is reviewed during the Annual Management Review process. This process is described in SOP– ‘Participation in External Quality Assessment Schemes’ - :SOP:QA:045.

5.7 Process Monitoring

Process monitoring is achieved by the application of internal quality controls. For laboratory test procedures specific controls will be defined within operational procedures. Such controls will be utilised to confirm the acceptability of results and the ongoing performance of tests.

5.8 Product Monitoring

Product Monitoring will be completed in keeping with respective regulatory requirements. This will be performed against product or component specifications. Monthly Component (Product) Quality Monitoring reports will be compiled and reviewed by relevant staff and in appropriate meetings. Such reports will identify where performance is less than satisfactory and as appropriate identify incidents to be managed through the Incident Reporting and Management Procedure.

5.9 Control of Non-Conformity

The management of non-conformances are detailed with procedures for a wide range of operations. Where there is not a definitive procedure an incident is logged. This ensures that

- The authority for the management of the nonconformities is designated.
- Remedial actions to be taken are defined.
- Operations are halted if necessary.
- The clinical significance is considered and if appropriate the user is informed.
- The products or results already released are recalled or identified.
- The responsible person for the resumption of examinations is defined.
- That each episode of nonconformity is documented & reviewed.

The results of the quality improvement programme forms part of the development, training and education of all staff.

Any serious non-conformity is reported through the ‘Procedure For Reporting and Management Of Quality Incidents’ SOP:QA:070 and onward to external bodies if deemed necessary. Where relevant changes to deliver quality improvement plans will be initiated through the ‘Change Control Procedure’. SOP:QA:081.

5.8 Corrective and Preventative Action

NIBTS apply corrective and preventive action in response non-conformances arising from the incident reporting system, internal audit and other sources.

5.9 Analysis of Data

NIBTS will use appropriate statistical analysis of data to ensure that processes remain in control. Specifically Statistical Process Control systems will be applied within component preparation.
### 6 Quality Management System Cross Reference

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**Quality Manual Ref**
- 3.4.2 Staff Orientation and Induction

**CPA**
- B4

**ISO 15189**
- 5.1

**HTA**
- 

**MHRA SMF Guidance**
- 

**EC Directive 2005/62/EC**
- 

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**Approved Date**: 29.01.2014

**Effective Date**: 14.02.2014

**Complied by**: G Geddis
- Quality Manager

**Approved by**: Mr G Bell
- Acting Chief Executive
## Site Quality (Master File) Manual

### 3.5 Human Resources/Personnel

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<td>3.5.3 Competence, Awareness, Training and Education</td>
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### 3.6 Infrastructure, Premises and Work Environment

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### 4. Process within NIBTS

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7 Change History

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| 01  | All  | New document which aims to collate the requirements of Quality Systems required for:  
|     |      | - Human Tissue (Quality and Safety) Regulations 2007  
|     |      | - Rules and Guidance for Pharmaceutical Manufacturers and Distributors  
|     |      | - Clinical Pathology Accreditation (UK) Ltd | G Geddis | 14.0510 |
| 02  |      | Revised Document to address – the “new” NIBTS Quality Function Structure, i.e. the creation of the Regulatory Affairs and Compliance department. Changes throughout document.  
|     |      | Update of key individuals – Page 58  
|     |      | Addition of specific sections on Change Control – Section 5.3 Page 42  
|     |      | Addition of cross reference to ISO 15189 Medical Laboratories – Particular Requirements for Quality and Competence  
|     |      | Update of SOP and policy references throughout the text | G Geddis | 01.08.11 |
| 03  | 1.1 - Page 8  
|     | 1.2 | Update of Activities Contracted Out  
|     | 1.3 | Inclusion at 1.2 of references to Medical Devices and Equipment Group  
|     | Appendices | Update on Management Representative re role of RAC Manager  
|     |      | Update of Organisational Charts | G Geddis | 02.04.13 |

Compiled by: Geoff Geddis, Quality Manager
Signature ___________________________ Date ____________

Approved by: Mr G Bell, Acting Chief Executive
Signature ___________________________ Date ____________
Appendix 1 – Organisational Structures / Charts

- Management Structure
- Donor Services
- HR & Corporate Services
- Finance & IM&T
- Laboratories
- Quality
- Regulatory Affairs & Compliance
- Medical Staff
- Key Staff Listing
Management Structure

Agency Board
Non-Executive Chairman & 3 Non-Executive Members

Chief Executive

- Laboratory Manager
- Finance & IM&T Manager
- Quality Manager
- Donor Services General Manager
- Head of HR & Corporate Services
- Regulatory Affairs and Compliance Manager (Responsible Person)
- Medical Director

Site Quality (Master File) Manual
FINANCE & IM&T DEPARTMENT

Finance Manager

Finance Analyst

Payments Officer

IM&T Manager

Senior IT Officer

IT Officer
QUALITY DEPARTMENT

Quality Manager

Head of Quality Control

Routine QC Lab
- 3 x BMS
- 2 - Band 7
- 1 – Band 6

Bacteriology Lab
- 1 x BMS
- Band 7

Business Continuity & Risk Manager

Information Governance Officer

1 x Admin & Clerical Support
REGULATORY AFFAIRS & COMPLIANCE DEPARTMENT

Regulatory Affairs & Compliance Manager

- Validation Officer
- IS Validation Officer
- RA & C Lead
- Audit Assistant
- Document Control Officer
- Compliance Officer
- Compliance Officer
MEDICAL STAFF

Medical Director

Consultant in Transfusion Medicine

1 x Speciality Doctor
2 x Staff Grade
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<tr>
<th>Post</th>
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<td><strong>Chief Executive</strong></td>
<td>Mr G Bell (Acting to the 28th February 2014) Dr K Morris (Absent)</td>
<td>CPA Clinical Lead Dr K Maguire (Consultant in Transfusion Medicine) in absence of Dr K Morris</td>
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<tr>
<td><strong>Medical Director</strong></td>
<td>Mr C Martyn (limited duties)</td>
<td>Operational duties performed by Dr K Maguire (Consultant in Transfusion Medicine)</td>
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<tr>
<td><strong>Laboratory Manager</strong></td>
<td>G Geddis (Acting to the 31st March 2014) Mrs C Ferguson (Absent)</td>
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<tr>
<td><strong>Finance Manager</strong></td>
<td>Mr G Bell (with Information Governance responsibilities until 31st March 2014)</td>
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<tr>
<td><strong>Quality Manager</strong></td>
<td>Mr G Geddis</td>
<td>Responsible Person (WDL) Designated Individual (HTA)</td>
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<td><strong>Donor Service General Manager</strong></td>
<td>Mr C Kinney</td>
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<tr>
<td><strong>Head of Human Resources and Corporate Services</strong></td>
<td>Mr I Ritchie (with Risk, Emergency Planning and Governance responsibilities until 31st March 2014)</td>
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<tr>
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<td>Ms A Macauley with relevant Quality Manager duties until 31st March 2014</td>
<td>Responsible Person (BSQR)</td>
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<td>Mr P Madden</td>
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<td><strong>Head of Microbiology</strong></td>
<td>Mr M Clarke</td>
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<tr>
<td><strong>Head of Hospital Services</strong></td>
<td>Ms P Gowdy</td>
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<td><strong>Head of Special Investigations</strong></td>
<td>Mr R Melanaphy</td>
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<td>Mrs H Kinghan</td>
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<td>Mr D Moore</td>
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<td>Facilities Operations Manager</td>
<td>Ms D Edgar</td>
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<td>Nurse Manager</td>
<td>Ms A O'Loughlin</td>
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<td>Ms C O'Doherty</td>
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<td>Donor Administration Manager</td>
<td>Mrs P Toal</td>
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<td>Donor Recruitment and Organisation Manager</td>
<td>Mr P McElkerney</td>
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