Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	COLIN O'LEARY	
3	DIRECTOR OF FINANCE	NOEL MURPHY	
3	QUALITY CONTROL HEAD OF DEPT IBTS	ENDA CADDEN	
3	QUALITY ASSURANCE REVIEWER IBTS	ELIZABETH GORDON	
3	QUALITY ASSURANCE REVIEWER IBTS	COLIN O'LEARY	
3	CHIEF EXECUTIVE OFFICE CE IBTS SD	ORLA O'BRIEN	
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	
3	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	
3	VALIDATION REVIEWER	PAUL HENDRICK	
3	QUALITY ASSURANCE REVIEWER IBTS	BERNADETTE CASEY	
3	HUMAN RESOURCES DIRECTOR SD IBTS	IDELLE HAWKINS	
4	DIRECTOR OF QUALITY	KAREN BYRNE	

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2	QUALITY ASSURANCE WRITER IBTS	COLIN O'LEARY	COLIN O'LEARY
3	VALIDATION REVIEWER	PAUL HENDRICK	SMARTCOMM
3	QUALITY ASSURANCE REVIEWER IBTS	ELIZABETH GORDON	SMARTCOMM
3	QUALITY ASSURANCE REVIEWER IBTS	COLIN O'LEARY	COLIN O'LEARY
3	CHIEF EXECUTIVE OFFICE CE IBTS SD	ORLA O'BRIEN	ORLA O'BRIEN
3	QUALITY ASSURANCE REVIEWER IBTS	KAREN BYRNE	REBECCA WALDEN
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
3	HUMAN RESOURCES DIRECTOR SD IBTS	IDELLE HAWKINS	IDELLE HAWKINS
3	DIRECTOR OF FINANCE	NOEL MURPHY	NOEL MURPHY
3	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS
3	TRAINED DIRECTOR OF QUALITY	KAREN BYRNE	REBECCA WALDEN
3	QUALITY CONTROL HEAD OF DEPT IBTS	ENDA CADDEN	ENDA CADDEN
3	QUALITY ASSURANCE REVIEWER IBTS	BERNADETTE CASEY	BERNADETTE CASEY
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
4	IT QM REVIEWER IBTS	ELIZABETH GORDON	ELIZABETH GORDON
4	VALIDATION HEAD OF DEPT	PAUL HENDRICK	PAUL HENDRICK

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Changes as described on Change Order:

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IBTS/CO/0005/21

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TITLE: IBTS QUALITY MANUAL

Change Description:
Revise IBTS/QA/QM/0001 [1]. Revise the IBTS Quality Manual to consider the BE and TE good practice guidelines and update to describe the overall IBTS quality management system to include Corporate Governance, Quality Management System Governance, Quality Objectives, Regulatory Requirements, Authorisations and Accreditations, Organisation Structure- (overall), Roles and Responsibilities (all Directors and QMS Management roles). In addition more general Quality System structures will be described to meet the requirements of Blood Establishment Good Practice Guidelines (Ref EU Directive 2016/1214) and the document will be structured using the Good Practice headings.

Reason for Change:
Reference CC 002/21/IBTS
Reference CC 022/21/IBTS

Change order No.:
IBTS/CO/0005/21

Referenced Procedures

IBTS/ADM/POL/0001	IBTS/QA/POL/0002	IBTS/QA/STD/0005	IBTS/QA/VMP/0001
IBTS/DIAG/UG/0002	IBTS/QA/POL/0003	IBTS/QA/STD/0006	IBTS/QA/VMP/0006
IBTS/DP/POL/0002	IBTS/QA/POL/0005	IBTS/QA/STD/0007	IBTS/QAV/POL/0001
IBTS/DP/POL/0018	IBTS/QA/POL/0007	IBTS/QA/STD/0008	IBTS/QAV/SOP/0001
IBTS/IT/DM/0001	IBTS/QA/QM/0002	IBTS/QA/STD/0024	IBTS/QAV/SOP/0002
IBTS/MBG/LM/0001	IBTS/QA/QM/0003	IBTS/QA/STD/0025	IBTS/RCI/LM/0001
IBTS/QA/AUTH/0001	IBTS/QA/QM/0004	IBTS/QA/STD/0026	IBTS/RR/BCP/0003
IBTS/QA/AUTH/0002	IBTS/QA/SOP/0014	IBTS/QA/STD/0027	IBTS/RR/BCP/0004
IBTS/QA/AUTH/0003	IBTS/QA/STD/0001	IBTS/QA/STD/0028	IBTS/RR/POL/0001
IBTS/QA/AUTH/0004	IBTS/QA/STD/0002	IBTS/QA/STD/0032	IBTS/RR/POL/0002
IBTS/QA/LIST/0002	IBTS/QA/STD/0003	IBTS/QA/STD/0033	IBTS/RR/POL/0003
IBTS/QA/POL/0001			

SmartSolve Roles

QA GEN IBTS	DA GEN IBTS
IT HD	

Training Type
Read only for all roles

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
Yes / No	Yes	Yes	Yes	Yes

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1 QUALITY POLICY*

The IBTS is committed to providing the following to all its users, donors, patients, hospital scientific and clinical staff the highest quality:

- blood and tissue products
- diagnostic and distribution services
- consultative services

The Quality Policy is implemented by the following:

- Implementation of a quality management system, the purpose of which is to continuously improve the quality of the products and services provided
- Setting quality objectives and plans to implement the quality policy
- Ensuring that all IBTS staff is familiar with the quality management system to ensure user satisfaction
- Upholding professional values and good professional practice
- Complying with all pertinent legislation

*A copy of this policy is also available as attachment 10.1 of this document. This copy is available for printing and displaying in IBTS business areas

2 INTRODUCTION

The Irish Blood Transfusion Service (IBTS) is a public sector body responsible for collecting, processing, testing, storage and distributing blood and blood products in Ireland. The IBTS is entirely dependant on the generosity of donors to achieve this objective. In addition, the IBTS processes and distributes corneas, heart valve, directed cord blood, ocular tissue and limbal stem cells. The IBTS orders, stores and distributes licensed medicinal products for the treatment of blood disorders.

The IBTS operates as a Blood Establishment under the terms of SI 360/05 (Licence # BE - 002), a Tissue Establishment under the terms of SI 158 / 06 (Licence # TE - 012). The IBTS also operates as a Manufacturing Authorisation Holder (Authorisation No.M11514 /00001) in accordance with 2001/83/EC and under the terms of the Medicinal Products (Control of Manufacture) Regulations 2007 to 2013 and S.I.No. 539 of 2007.

The Functions of the Irish Blood Transfusion Service under Statutory Instrument No. 78 of 1965 as amended are:

- to organise and administer a blood transfusion service including the processing or supply of blood derivatives or other blood products, and also including blood groups and other tests in relation to specimens of blood received by the Board.
- to make available blood and blood products.
- to make available equipment or reagents suitable for use in relation to the service
- to furnish advice, information and assistance in relation to any aspect of the service to the Minister, any health authority or any hospital authority.
- to make any necessary provision for publicity in relation to the service.
- to organise, provide, assist or encourage research and the training of persons in matters relating to blood transfusion and preparation of blood products.
- to co-operate with other bodies with analogous scientific functions.
- to organise and administer a service for obtaining and assessing reports of unexpected or undesirable effects of transfusion of blood or blood components made available by the Board, including the furnishing to the Health Products Regulatory Authority (HPRA) of reports of any unexpected or undesirable effects of any transfusion of such blood or blood components.

To fulfil its statutory functions the IBTS conducts the activities of collection, processing, testing, storage and distribution of blood and blood products as outlined in the Blood Establishment Manual, IBTS/QA/QM/0002.

To fulfil its statutory functions, Tissue activities are conducted at the IBTS NBC (National Blood Centre) as outlined in the Tissue Establishment Manual, IBTS/QA/QM/0003.

To fulfil its statutory functions, Good Distribution Practice (GDP) wholesaling activities are conducted at IBTS NBC (National Blood Centre) and MRTC (Munster Regional Transfusion Centre) facilities as described in the GDP Manual, IBTS/QA/QM/0004

Corporate Governance

Compliance with the code of practice for the governance of state bodies

The IBTS Board is committed to complying with the relevant provisions of the code of practice for the Governance of state bodies, Department of Public Expenditure and Reform in 2016. The IBTS Board review reports on internal controls during the year along with regular reviews of the reports of the Health Products Regulatory Authority (Competent Authority for Blood, Tissue and GDP in Ireland) on operational and compliance controls and risk management. The board will continue to review these reports and to work closely with the IMB to ensure the highest international standards.

Workings of the Board

The board is comprised of twelve members including a non-executive chairperson appointed by the Minister of Health and Children. The board meets 6 times a year. All members receive appropriate and timely information, to enable the board to discharge its duties. The board takes appropriate independent, professional advice as necessary.

Medical Advisory Committee

The Medical Advisory Committee (MAC) reports to the Board of the IBTS and is comprised of the medically qualified members of the Board and the medical consulting staff. The Medical Advisory Committee meets on a monthly basis. Its function is to monitor developments and develop policies relevant to the field of transfusion medicine and related fields and to inform the board of any such developments and to advise the board on appropriate action. Items from the IBTS National Consultant meetings and Infection Sub-group are brought to the MAC where required.

The IBTS Quality Manual defines at a high level the agreed strategy for the execution of the organisations approach to a Quality Management System. The IBTS Quality Manual has been developed under the authorisation of the Director of Quality and Compliance. The hierarchical Quality Management System documentation structure is outlined in **Figure 1** below. The Quality Manual will be reviewed every two years.

Quality Manual Documentation Structure

The Overall IBTS Quality Manual describes the overall IBTS quality management system to meet the requirements of Blood Establishment Good Practice Guidelines (Ref EU Directive 2016/1214) and the document will be structured using the Good Practice headings. This is chosen as the most appropriate structure as the IBTS primarily operates as a Blood Establishment.

Further IBTS manuals will refer to the overall IBTS Quality Manual for general quality system description. Detailed and specific further descriptions where required will be included in the additional manuals with reference to further regulatory or accreditation requirements. The hierarchy of documents is described in Figure 1 below. This IBTS quality manual falls within the document hierarchy as a policy level document (level 1). Policy documents can be further divided along hierarchical system as described in Figure 2. The IBTS Quality Manual is the highest level policy document.

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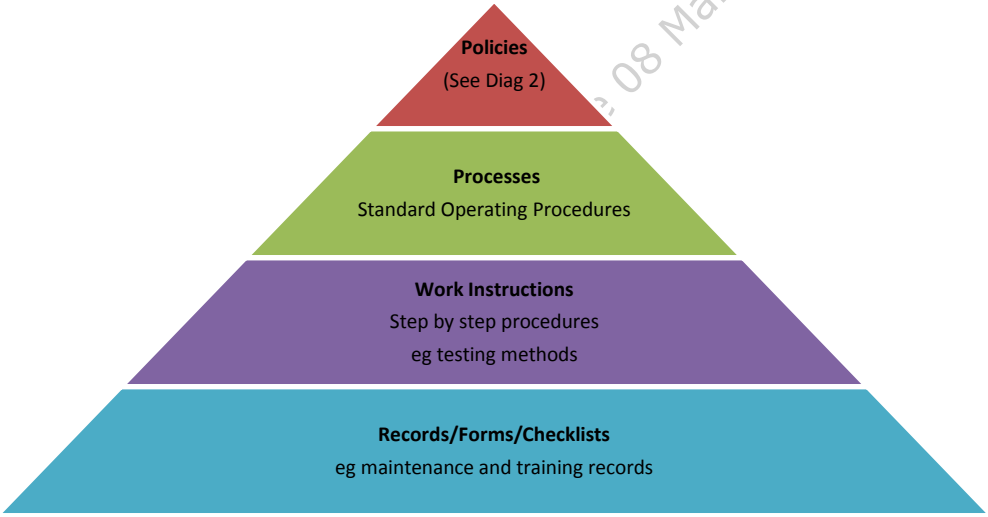

Figure 1: Overall Documentation Hierarchy

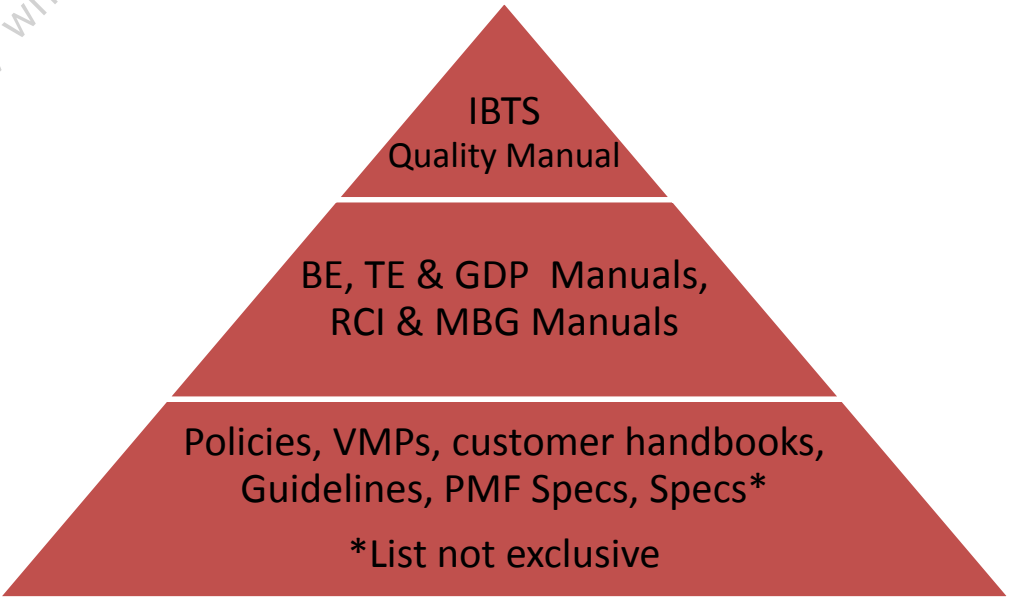

Figure 2: Expansion of Policies Level 1 from Diagram 1

3 QUALITY OBJECTIVES

The following are the objectives of the IBTS Quality Manual:

- To define and develop the IBTS Quality System to comply with regulatory requirement
- To define the IBTS Organisational Structure with respect to Quality Management System and Regulatory Requirements
- To define the roles / responsibilities of the IBTS Personnel associated with the Quality Management System
- To define the roles / responsibilities of the IBTS Personnel associated with the approval of this document
- To define the IBTS Quality System Methodology

4 REGULATORY REQUIREMENTS

- Blood Directive – Directive 2002/98/EC ~ "Setting the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC".
- Technical Directive - Directive 2004/33/EC ~ "Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components"
- Technical Directive - Directive 2005/61/EC ~ "Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events".
- Technical Directive - Directive 2005/62/EC ~ "Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards community standards and specification relating to a quality system for blood establishments".
- Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life
- Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations
- Commission Directive 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments. (The Good Practice Guidelines are available as IBTS/QA/STD/0001 for reference)
- SI 360/2005 - European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005.
- SI 179/2008 - European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2008
- SI 207/2009 - European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2009

- SI 329/2011 - European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2011
- SI 562/2006 - European Communities (Quality System for Blood Establishments) Regulations 2006
- SI 547/2006 - European Communities (Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations 2006
- SI 494/2015 - European Communities (Quality and Safety of Human Blood Components) (Amendment) Regulations 2015
- Directive 2001/83/EC - Good Distribution of Medicinal Products for human Use
- cGMP: - Directives Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use.
- Tissue Directive – Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Technical Directive – Directive 2006/17/EC – implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.
- Technical Directive – Directive 2006/86/EC – implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.
- Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells
- Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells
- Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive
  2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells
- 2010/453/EU: Commission Decision of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council (notified under document C(2010) 5278)
- Commission Decision of 3 July 2015 establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code
- SI 158 /2006 – European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006

- SI 598/2007 - European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007
- SI 209/2014 · European Communities (Quality and Safety of Human Tissues and Cells) (Amendment) Regulations 2014
- SI 32/2019 giving effect to Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells.
- SI 33/2019 giving effect to Commission Directive (EU) 2015/5661 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.
- Directive 2001/83/EC - EU Good Distribution Practice for Medicinal Products for Human Use.
- Directive 2011/62/EU- Directive 2011/62/EU amending Directive 2001/83/EC on the community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.
- Directive 2016/161/EU - Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC.
- Regulation (EC) No 1394/2007 of the European Parliament and of the council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.
- Commission Regulation (EC) No 668/2009 of 24 July 2009 implementing Regulation (EC) No 1394/2007 of the European Parliament and of the Council with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises.
- Regulation (EU) No 1235/2010 of the European Parliament and of the council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

Additional standards and guidelines are listed in further IBTS business area manuals where relevant to that area.

5 AUTHORISATIONS AND ACCREDITION

A schedule of appropriate regulatory authorisations and quality system accreditations held by the IBTS is listed in **Attachment 10.2.** The current authorisations are available from SmartSolve.

6 ORGANISATION STRUCTURE

The Organisation Structure of the IBTS is outlined in **Attachment 10.3**.

7 RESPONSIBILITIES

The following are the key organisational roles and their associated responsibility with respect to Quality within the organisation.

Role	Responsibility within the Quality System
Chief Executive	The responsibility of the Chief Executive is to ensure Senior Management commitment to the Quality Management System at the IBTS.
Director of Quality & Compliance	The responsibility of the Director of Quality / Compliance is to ensure that the Quality Management System is implemented across the organisation and that regulatory requirements are met.
Medical and Scientific Director	The responsibility of the Medical and Scientific Director is to ensure the Quality Management System is appropriately supported and implemented in all medical and scientific functions of the IBTS. The further responsibility of the Medical and Scientific Director is to ensure that approved medical policies are implemented consistently across the organisation.
Director of Operations	The responsibility of the Director of Operations is to ensure that appropriate operational resources are made available to fully implement the Quality Management System in their area of responsibility
Director of Finance	The responsibility of the Director of Finance is to ensure appropriate financial resources are made available to implement the Quality Management System. The further responsibility of the Finance Director is to ensure the Quality Management System is fully implemented in their associated area of responsibility.
Director of Human Resources	The responsibility of the Human Resource Director is to ensure appropriate human resources are made available to implement the Quality Management System. The further responsibility of the Human Resources Director is to ensure the Quality Management System is fully implemented in their associated area of responsibility.

The following are the key Quality System Management roles and their associated responsibility with respect to Quality within the organisation.

Role	Responsibility within the Quality System
National Quality Assurance Manager	The National Quality Assurance Manager is responsible for the effective implementation of the Quality Management System across the organisation.
Validation Manager	The responsibility of the Validation Manager is to implement the Quality Management System across the organisation with respect to Management of Validation , Equipment Maintenance & Calibration
IT Quality Manager	The responsibility of the IT Quality Manager is to implement the Quality Management System across the organisation with respect to the IT department and computer systems.
Quality Compliance and Regulatory affairs Manager	The responsibility of the Quality Compliance and Regulatory affairs Manager is to ensure the Quality Management System meets international best practice, GMP & regulatory requirements across the organisation. This includes management of Internal and external inspections to drive continuous improvement.
Quality Control Manager	The responsibility of the QC Manager is to implement the Quality Management System across the organisation with respect to Quality Monitoring, Environmental Monitoring AND Materials Management.

8 IBTS QUALITY SYSTEM

The IBTS Quality Manual has been subdivided into the following sections to meet the current Regulatory Requirements as described in the Good Practice Guidelines. Each section will define the IBTS quality management system approach. This describes the overall quality management system in the organisation. Detailed and specific aspects of the quality management system for specific areas of IBTS business are described in the relevant manuals as described in the introduction to this document.

8.1 Quality System– General

The Quality System encompasses the following;

- quality management
- quality assurance
- continuous quality improvement
- personnel
- premises & equipment
- documentation
- collection

- testing
- processing
- storage
- distribution
- quality control including statistical process control
- recall
- external and internal auditing
- contract management
- non-conformance
- self –inspection
- training

The IBTS will operate a system of Quality Management for the following:

- the collection, testing, processing, storage and distribution of human blood and blood products.
- the testing, processing, preservation, storage and distribution of human tissues.
- Manufacturing of limbal stem cells
- wholesaling of Medicinal Products for Human Use.
- Provision of referral testing services i.e., National Histocompatibility and Immunogenetics Reference Laboratory and Blood Group Genetics Laboratory in the Molecular Biology and Genetics department, MRTC Diagnostics Laboratory and the Red Cell Immunohaematology Laboratory.

The Quality Management System will be defined in this document and will be implemented through associated further manuals, policies, plans and procedures described and referenced in this quality manual.

8.2 Quality System – Good Practice

Good Practice is the part of Quality Management that ensures that blood, blood components and tissue are produced and controlled consistently to the quality standards appropriate to their intended use. The IBTS will operate according to good practice by;

- Clearly defining all processes and ensuring they are reviewed systematically
- Ensuring the requirements for Quality Control are adhered to
- Performing quality reviews of all blood and tissue products according to defined procedure.

8.3 Quality System – Quality Risk Management

The Executive Management Team (EMT) has the overall responsibility for all aspects of Risk Management in the IBTS. The appointed Risk and Resilience Manager provides the necessary guidance and support to

fulfil these requirements. The IBTS Risk Management policy (IBTS/RR/POL/0002) describes:

- the objectives of IBTS risk management arrangements;
- compliance with risk management;
- risk management principles;
- roles and responsibilities;
- escalation, reporting and review of risks, and;
- risk appetite statement.

In addition quality risk management is embedded in all areas of the quality system and is described in the individual policies and procedures that cover each area. E.g. Quality Risk Management in Change Management is described in IBTS/QA/POL/0001

8.4 Personnel & Organisation

The Human Resources Department of the IBTS have in place personnel and recruitment policies. Refer to IBTS HR Policies and Procedures Manual located at:
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The IBTS will ensure that all Personnel are sufficiently qualified and trained for tasks they are expected to perform. Job descriptions are developed to individually define the high level responsibilities. Additional specific detailed responsibility will be defined in the specific plans / standard operating procedures to which the personnel are expected operate to. All individuals will be made aware of best practice principles.

The IBTS will ensure that at a minimum procedural based training will be conducted and where necessary competency based training. This is described in IBTS/QA/POL/0007.

8.4.1. Responsible Person (Blood) – The IBTS will designate a person who is responsible for the following functions (Ref Directive 2002/98/EC):

- ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State,
- providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures as required in Article 5,
- the implementation of the requirements of Articles 10, 11, 12, 13, 14 and 15 in the blood establishment.

8.4.2. Responsible Person (Tissue) – The IBTS will designate a person who is responsible for the following functions (Ref Directive 2004/23/EC)**:**

- ensuring that human tissues and cells intended for human applications in the establishment for which that person is responsible are procured, tested, processed, stored and distributed in accordance with this Directive and with the laws in force in the Member State;
- providing information to the competent authority or authorities as required in Article 6;
- implementing the requirements of Articles 7, 10, 11, 15, 16 and 18 to 24 within the tissue establishment.

8.4.3. Responsible Person (GDP) – The IBTS will designate a person who is responsible for the following functions:

- ensuring that a quality management system is implemented and maintained;
- focusing on the management of authorised activities and the accuracy and quality of records;
- ensuring that initial and continuous training programmes are implemented and maintained;
- coordinating and promptly performing any recall operations for medicinal products;
- ensuring that relevant customer complaints are dealt with effectively;
- ensuring that suppliers and customers are approved;
- approving any subcontracted activities which may impact on GDP;
- ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;
- keeping appropriate records of any delegated duties;
- deciding on the final disposition of returned, rejected, recalled or falsified products;
- approving any returns to saleable stock;
- ensuring that any additional requirements imposed on certain products by national law are adhered to.

8.4.4. The IBTS will ensure that the responsible person fulfils the regulatory requirement for qualifications, experience and knowledge. In the absence of the responsible person the IBTS has nominated a delegate.

8.4.5. The Responsible Person for the Blood and Tissue establishments and wholesaling and distribution authorisations (GDP) are listed in the relevant authorisations. The list of authorisations is contained in Attachment 6.2.

8.4.6. Laboratory Director Red Cell Immunohaematology Laboratory – The IBTS will designate a person with the competence and delegated responsibility for the services provided. This is further described in IBTS/RCI/LM/0001.

8.4.7. Laboratory Director Molecular Biology and Genetics Laboratory – The IBTS will designate a person with the competence and delegated responsibility for the services provided. This is further described in IBTS/MBG/LM/0001

8.5 Premises

The IBTS will ensure that Premises / Facilities will be located, designed, constructed, adapted and maintained to suit the operations to be carried out. The IBTS will ensure where possible the layout and design will aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid any adverse effect on blood component, tissue and cell product.

8.6 Equipment & Materials

The IBTS will ensure that Equipment / Systems will be located, designed, constructed, adapted and maintained to suit the operations carried out. The IBTS will ensure where possible the layout and design will aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid any adverse effect on tissue and cell product.

8.6.1 Data processing systems (Computerised Systems)

If computerised systems are used, software, infrastructure and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Infrastructure and software must be protected against unauthorised use or unauthorised changes. The back-up procedure must prevent loss of or damage to data at expected and unexpected down-times or function failures (Directive/2005/62/EC/Annex 4.5).

The IBTS will ensure computer systems are properly maintained at all times with a documented maintenance strategy. All changes to computerised systems will be validated and maintained in a validated state. The IBTS will ensure data is protected with safeguards in place to prevent unauthorised

additions, deletions or modifications of data and transfer of information are in place to resolve data discrepancies, and to prevent unauthorised disclosure of such information.
There will be a hierarchy of permitted user access to enter, amend, read or print data. To prevent unauthorised access, there will be personal passwords in place on computer systems that are changed regularly. Further information is described in the IT Manual, IBTS/IT/DM/0001.

8.6.2 Qualification & Validation

The IBTS will identify all equipment / systems / processes which have a direct or indirect impact on Blood / Tissue product quality that require validation.
The IBTS has developed a Validation Master Plan (IBTS/QA/VMP/0001) and associated Validation Matrix to validate all equipment / systems / processes identified as having a direct or indirect impact on Blood / Tissue product quality.
The IBTS has developed a Calibration / Maintenance Master Plan (IBTS/QA/VMP/0006) to ensure the validated state of equipment / systems are maintained.

8.6.3 Process Validation

The IBTS will have a system in place to cover the initial validation of new processes, subsequent validation of modified processes or site transfers for maintaining of the validated state (ongoing process verification) with reference to IBTS/QA/VMP/0001. Retrospective validation will not be accepted.
Process validation of new blood components or tissue will cover all intended processes and sites of manufacture. During process validation the IBTS will establish
establish whether all quality attributes and
process parameters, which are considered important for ensuring the validated state and acceptable blood component or tissue quality, can be consistently met by the process.

8.6.4 Validation of test methods

The IBTS will ensure all analytical test methods used in qualification or validation exercises are validated with an appropriate detection and quantification limit as described in IBTS/QA/VMP/0001.

When microbial testing of blood components or tissue is performed, the method will be validated to confirm that the product or residues, e.g. antibiotics, do not interfere with the analysis and influence the recovery of microorganisms.
When microbial testing of surfaces is carried out, validation will be performed on the test method to confirm that sanitising agents do not influence the recovery of microorganisms.

8.6.5 Change Control

The IBTS will ensure the change management process will describe the actions to be taken if a planned change is proposed for a starting material, blood component specification, tissue specification, process, equipment, environment (or site), product range, method of production or testing or any other change that may affect donor safety, blood or tissue component quality or reproducibility of the process with reference to IBTS/QA/POL/0001.
Quality risk management will be used to evaluate planned changes to determine the potential impact on blood component or tissue quality, the blood or tissue establishment's quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences and to plan for any necessary process validation, verification or requalification efforts.

8.6.6 Control of equipment & materials

The IBTS will ensure there is a documented system for purchasing equipment and materials is available as per specific departmental operating procedures. The specific requirements for establishing and reviewing contracts for the supply of both equipment and materials is described in IBTS/ADM/POL/0001.
The calibration and maintenance of equipment is defined in IBTS/QA/VMP/0006 and specific departmental operating procedures and requalification documents.

8.6.7 Materials Management

The IBTS will operate a system of Materials Management. Requirements will be defined in specific departmental operating procedures.
Testing and management of critical materials for blood and tissues will be defined in dedicated standard operating

procedure(s) and critical starting material lists with reference to Material Specifications.

8.7 Documentation

8.7.1 Required good practice documentation

The IBTS will ensure current documents exist that set out specifications, procedures and records covering each activity undertaken in the blood and tissue establishment are kept up-to-date.

The IBTS documentation and record management policies are described in IBTS/QA/POL/0002 and IBTS/DP/POL/0018.

8.7.2 Generation & Control of documentation

The IBTS will establish a system of document control, through which the IBTS will take all necessary measures to ensure that the quality system includes at least documentation on the following: –

(i) policies

(ii) SOPs

(iii) guidelines,

(iv) user guides

Customer handbooks

(v) training and reference manuals,

(vi) reporting forms,

(vii) donor records, and

(vii information on the final destination of blood products, tissues and cells.

The IBTS will ensure that this documentation is readily available for inspection by the Competent Authority.

8.7.3 Good documentation practice

The IBTS will follow good documentation practice in all areas of the IBTS as laid out in IBTS/QA/POL/0002 and associated standard operating procedures.

8.7.4 Retention of documents

The IBTS will prescribe to a defined system for the retention and control of documentation as described in IBTS/DP/POL/0002.

8.7.5 Specifications

The IBTS will ensure there are current, authorised specifications for starting and packaging materials, as well as finished tissue, blood and blood components. The finished tissue and blood components specifications are detailed in the IBTS/QA/QM/0002 and IBTS/QA/QM/0003.

8.7.6 Preparation Instructions

The IBTS will ensure there are approved written instructions for preparation of each blood components and tissue / cell that is produced as per IBTS/QA/QM/0002 and IBTS/QA/QM/0003

8.7.7 Labelling

Through the use of product master file specifications and current manuals; IBTS/QA/QM/0002 and IBTS/QA/QM/0003, the IBTS will ensure that labelling should identify the individual components and their nature clearly at all stages of production.

8.7.8 Procedures & Records

With departmental operating procedures the IBTS will ensure there are written procedures and records for the receipt of each delivery of materials and reagents that can impact on the quality and safety of blood and blood components and tissues / cells.

The Materials Management department will manage operating procedures and starting materials lists for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials.

The Tissue Bank in conjunction with the Materials Management department will manage operating procedures and starting materials lists for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials relating to Tissues and cells.

8.7.9 Sampling

The IBTS will ensure that procedures exist with reference to IBTS/QA/QM/0002 and IBTS/QA/QM/0003 for the following;

- Sampling
- Quality monitoring
- Testing of materials, blood components, tissues and cells at different stages of processing.

8.7.10 Other

The IBTS will ensure as detailed in the appropriate manual - IBTS/QA/QM/0002, IBTS/QA/QM/0003 or IBTS/QA/QM/0004 the following are available;

- Procedures for release and rejection of blood, blood components, tissue and cells
- Records of the distribution of blood, blood components, tissue and cells and medicinal products to facilitate any necessary recall with reference to IBTS/QA/POL/0005.
- Records are kept for major or critical analytical testing, processing equipment, and areas where blood components or Tissue and cells have been processed.

The IBTS will ensure the non conformance policy, IBTS/QA/POL/0003 and associated SOP's allow recording of actions and conclusions reached where there have been issues with any of the following;

- validation and qualification of processes, equipment and systems
- equipment assembly and calibration;
- maintenance, cleaning and sanitation;
- personnel matters, including signature lists, training in Good Practice and technical matters, clothing and hygiene, and verification of the effectiveness of training;
- environmental monitoring;
- pest control;
- complaints;
- recalls;
- returns;
- change control;
- investigations of deviations and non-conformances;
- audits of compliance with internal quality/Good Practice;
- summaries of records, where appropriate (e.g. review of the
- quality of blood components);
- supplier audits.

8.8 Blood and Tissue / Cells collection, testing & processing

8.8.1 Donor selection and eligibility

The IBTS shall ensure donor selection and eligibility for blood components is performed as described in the BE manual and relevant Medical Guidelines.

8.8.2 Collection of blood & blood components & Tissue / Cells

The IBTS will ensure the collection and processing of blood & blood components & Tissue / Cells is performed as detailed in IBTS/QA/QM/0002 and IBTS/QA/QM/0003

8.8.3 Laboratory testing

Additional Quality Control Testing / Monitoring

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for quality control testing where appropriate for blood products and tissue.

Patient Service Testing – Red Cell Immunohaematology Testing

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for patient service testing – where appropriate. See IBTS/RCI/LM/0001 and IBTS/DIAG/UG/0002 for further detail.

Patient Service Testing – Molecular Biology and Genetics

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for testing as described in the IBTS/MBG/LM/0001.

8.8.4 Testing for infectious markers

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures where appropriate for blood products and tissue for the following as described in IBTS/QA/QM/0002 and IBTS/QA/QM/0003;

- Viral Screening of virology markers
- NAT testing of virology markers
- Bacterial screening tests

8.8.5 Blood group serological testing of donors & donations

Donor Grouping

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for Donor Grouping Testing where appropriate for blood products as described in the IBTS/QA/QM/0002.

8.8.6 Processing & validation

The IBTS will ensure the following as described in IBTS/QA/VMP/0001and the BE and TE manuals;

- All equipment is used according to validated procedures
- Processing of blood components, tissue and cells is performed using appropriate and validated procedures
- Closed systems are used for processing where possible
- Freezing processes are validated according to worst case scenarios

- Sterile connecting devices are used according to the validated procedures.

8.8.7 Labelling

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for blood products and tissue labelling and packaging with reference to IBTS/QA/QM/0002 or IBTS/QA/QM/0003.

8.8.8 Release of blood & blood components and Tissue

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for the release of blood products and tissue with reference to IBTS/QA/QM/0002 or IBTS/QA/QM/0003

8.9 Storage & Distribution

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for blood products and tissue storage with reference to IBTS/QA/QM/0002 and IBTS/QA/QM/0003 that will ensure

- that personnel directly involved in activities relating to the storage of blood products and tissue are qualified to perform such tasks and shall be provided with the appropriate training
- that all procedures associated with the storage of products are documented in the standard operating procedures and that the storage conditions comply with predetermined acceptance criteria
- procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of blood products and tissue

Under the Quality Management System, the IBTS will maintain policies / standard operating procedures for management of blood products and tissue distribution with reference to IBTS/QA/QM/0002 and IBTS/QA/QM/0003.

8.10 Outsourced Activities Management

The IBTS will establish written agreements with a third party each time an external activity takes place which influences the quality and safety of blood products and tissue processed in cooperation with a third party, and in particular in the following circumstances with reference to IBTS/ADM/POL/0001;

(a) where the IBTS entrusts one of the stages of blood products or tissue processing to a third party,

(b) where a third party provides goods and services that affect blood products or tissue quality and safety assurance, including their distribution,
(c) where the IBTS distributes blood products or tissue processed by third parties.
(d) where the IBTS provides blood products / tissue to hospitals
(e) where the third party provides referral testing services for patient service testing.

8.10.1 The contract giver

The IBTS shall evaluate and select third parties on the basis of their ability to meet the standards laid down in the appropriate EU Blood and Tissue Directives.

The IBTS shall keep a complete list of the agreements that they have established with third parties.

The IBTS will ensure all relevant information is provided to the contract acceptor to ensure contracted operations are performed as required in the contract.

8.10.2 The contract acceptor

Where the IBTS entrusts a third party to carry out work on their behalf they will ensure the contract acceptor has adequate premises, equipment, knowledge, experience and competent personnel.

The contract acceptor will not pass to a third party any of the work entrusted under the contract without prior evaluation and approval of the arrangements by the IBTS. Arrangements made between the contract acceptor and any third party should ensure that the relevant blood or tissue collection, processing and testing information is made available in the same way as between the original contract giver (IBTS) and contract acceptor.

8.10.3 The contract

The IBTS will ensure that all contracts with third parties specify their respective responsibilities relating to the contracted operations.

The contract will ensure all arrangements for blood or tissue collection, processing and testing are in compliance with the requirements of Good Practice and regulatory requirements and agreed by both parties.

The contract will specify detailed procedures for the IBTS and the contract acceptor.

The contract will clearly describe who is responsible for purchasing materials, testing and releasing materials, undertaking blood or tissue collection, and for processing and testing (including in-process controls). Where analyses are sub-contracted, the contract will state the arrangements for the collection of samples and the contract acceptor will understand that they may be subject to inspections by the Competent Authority.
The IBTS will ensure any records relevant to assessment of the quality of the blood, tissue or a blood component in the event of complaints or a suspected defect are be accessible and specified in the IBTS defect/recall procedures.
The contract will permit the IBTS to audit the facilities of the contract acceptor.
The agreements between the IBTS and third parties will be available for examination by the Competent Authority.

8.11 Non-Conformance & Recall

8.11.1 Deviations & CAPA

Under the Quality Management System, the IBTS will operate an incident reporting system. This will be implemented through standard operating procedure with reference to the policy, IBTS/QA/POL/0003. The incident reporting system will define and categorise incidents, manage incident corrective / preventative actions and track / trend incident reports.

8.11.2 Complaints

The IBTS will operate a complaints system. This will be implemented through standard operating procedure with reference to the policy, IBTS/QA/POL/0003. The complaint reporting system will define and categorise complaints, manage associated corrective / preventative actions and track / trend complaints. The complaint system will operate for donor / service and product complaints.

8.11.3 Recall

Serious Adverse Event / Recall

The IBTS will ensure that all serious adverse events and reactions will be notified to the competent authority. The IBTS will manage this through its vigilance procedures IBTS/QAV/SOP/0001 and IBTS/QAV/SOP/0002.

The notification will report

- any serious adverse events and reactions which may have an influence on the quality and safety of blood products and tissues and / or which may be attributed to blood products collected, tested, processed, stored and distributed or which may be attributed to the procurement, testing, processing, preservation, storage and distribution of tissues.
- any serious adverse reactions observed during or after clinical applications, which may be linked to the quality and safety of blood products collected, tested, processed, stored and distributed and tissues tested, processed, preserved, stored or distributed.

The IBTS shall

- ensure that an accurate, rapid and verifiable recall from distribution any product which may be related to any serious adverse event, and
- keep a record of its activities, including the types and quantities of blood products collected, tested, processed, stored and distributed and tissues, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues intended for human applications.

The IBTS will operate a system to ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any Blood Products or Tissues that are found to be in non conformance with procedures / specifications. This will be implemented through standard operating procedure with reference to IBTS/QA/POL/0005.

The IBTS will ensure there is a system in place for the recall of medicinal products as described in the GDP Manual with reference to the appropriate IBTS/QA/SOP/0014

8.12 Self-inspection, audits & improvement

Under the Quality Management System, the IBTS will operate an Internal / External Audit Process with reference to IBTS/QA/POL/0006. This will be implemented through standard operating procedure. The IBTS will annually create and execute an Internal / External Audit schedule.

8.13 Quality Monitoring & Control

8.13.1 Quality monitoring

IBTS operates a quality monitoring programme as described in IBTS/QA/QM/0002 and IBTS/QA/QM/0003. Specific Quality Monitoring Requirements are listed in the individual blood and tissue components specifications

8.13.2 Quality control

The IBTS will operate a system of Quality Control. This will be implemented through standard operating procedure(s). The Quality Control procedures will define sampling, specifications and testing associated with

- Blood Products throughout the collection, testing, processing, storage and distribution of human blood and blood products.
- Tissues throughout the procurement, testing, processing, preservation, storage and distribution of tissues and cells.

These will be defined in the specific department procedures. Batch acceptance testing and management of critical materials for the blood, tissues will be defined in dedicated standard operating procedure(s).

8.14 Quality Management – Change Control

Under the Quality Management System, the IBTS will operate a Change Management system as described in IBTS/QA/POL/0001.This will be implemented through standard operating procedure. The change control system will ensure that an effective change management process is in place for any significant change requested under the Quality System or any change which has a direct or indirect impact to Product quality.

8.15 Regulatory Authorisation

See section 4 and 5 for description of regulatory requirements and authorisations.

The IBTS provides an annual report to the Competent Authority (HPRA) to comply with authorisation requirements for both the blood and tissue operations.

8.16 Traceability

The IBTS will operate a system of traceability, through which the IBTS will take all necessary measures to ensure that

- all blood and tissues, which it procures, processes, stores or distributes, can be fully identified and traced from donor to end user, or disposal, and vice versa, in accordance with the Irish Regulations and as detailed in IBTS/QA/QM/0002, IBTS/QA/QM/0003 and IBTS/RCI/LM/0001. This traceability will also apply to all relevant data relating to products and materials coming into contact with these tissues and cells as described in IBTS/DP/POL/0002.
- a donor identification system which assigns a unique numeric or alphanumeric donation indication, to each of the products associated with it
- use a labelling system that contains the information or references

The IBTS shall keep the traceability records and additional records which are necessary as defined in IBTS/DP/POL/0002 -

- for the identification and traceability of each single blood component, tissue donation and each single blood component, tissue unit and its products and products coming into contact with these blood products, tissues,
- to ensure full traceability from donation and procurement, processing or storage to the point of delivery to a hospital or site, and at all stages,
- for a period of not less than 30 years after clinical use.

The IBTS shall ensure that the labelling, documentation and packaging on all blood and blood products and on each tissue supplied shall conform to the requirements in SI 360/05 and SI 158/06.

This will be implemented through standard operating procedure(s).

8.17 Import / Export

The IBTS shall ensure that imported blood component products and tissues as described in the relevant manuals; IBTS/QA/QM/0002, IBTS/QA/QM/0003 and IBTS/RCI/LM/0001.-

(a) can be traced in both directions from donor to the recipient in accordance with the requirements in the EU Blood and Tissue Directives,

(b) meet standards of quality and safety equivalent to those laid down in the EU Blood and Tissue Directives and IBTS Quality Standards.

The IBTS shall ensure that exported blood component products and tissues as described in the relevant manuals; IBTS/QA/QM/0002, IBTS/QA/QM/0003 and IBTS/RCI/LM/0001.-

(a) meet standards of quality and safety equivalent to those laid down in the EU Blood and Tissue Directives and IBTS Quality Standards,

(b) have a clear fating with respect to traceability.

8.18 Data Protection / Confidentiality

The IBTS through the implementation of IBTS/DP/POL/0001 and associated policies and standard operating procedures ensures that all information, which is collected is held securely so that it is

- available for the purpose of tracing donations,
- Subject to safeguards against unauthorised additions, deletions or modifications to donor files or deferral records and transfer of information.
- disclosed under identified exceptions

The IBTS will ensure that procedures to resolve data discrepancies are in place.

The IBTS will ensure that the identity of the recipient of tissue is not disclosed to the donor or his family and vice versa, without prejudice to any national law which may come into force on the conditions for disclosure.

8.19 Reception

The IBTS will as described in IBTS/QA/QM/0002 and IBTS/QA/QM/0003;

- ensure that blood products, tissue and cells and associated documentation comply with the requirements set out in SI 360 of 2005 and SI 158 of 2006.
- verify and record the fact that the packaging of blood products and tissue is received complies with the requirements set out in SI 360 of 2005 and SI 158 of 2006.
- ensure that blood components and tissues that do not comply shall be appropriately managed.
- document the acceptance or rejection of received blood products and tissue
- blood products and tissue are correctly identified at all times. Each delivery or batch of blood products and tissues shall be assigned an identifying code
- hold blood product and tissue in quarantine until such time as the

requirements relating to donation, testing and information have been met in accordance with procedure / specification

8.20 Business Continuity

The IBTS will ensure Business Continuity through the following IBTS Policies and associated Business Continuity Plans;
IBTS/RR/POL/0001
IBTS/RR/POL/0003

8.21 Health and Safety

The IBTS will ensure Health and Safety at the Organisation through the Health and safety policies managed by the Health & Safety (H&S) Manager. These are controlled under the direction of the H&S Manager.

8.22 Haemovigilance / Tissue Vigilance

The IBTS will operate a Haemovigilance and Tissue Vigilance system with reference to the vigilance policy, IBTS/QAV/POL/0001. These are managed by the IBTS BioVigilance Officer.

8.23 Therapeutic Services

The IBTS will operate Therapeutic Services in the MRTC region. This will be implemented through standard operating procedure(s).

8.24 Contingency Arrangement

The IBTS will ensure Business Continuity through the following IBTS contingency plans;

IBTS/RR/BCP/0003 and IBTS/RR/BCP/0004

8.25 Import of Rare Blood & Components from non-EEA countries

The IBTS will describe the policies relating to import of rare blood components from non-EEA countries in the relevant BE, TE and RCI manuals.

9 REFERENCES

The following references were used in the development of this document:

- Regulatory Requirements as listed in section 4
- ISO 9001 – Quality Management Systems
- ISO 15189 - Medical Laboratories – Particular requirement for Quality and Competence.
- Council of Europe, Guide to the preparation, use and quality assurance of blood components, current edition.
- Council of Europe, Guide to the quality and safety of tissues and cells for human application, current edition.
- Guidelines for the Blood Transfusion Services in the UK, current edition
- PIC/S GMP Guide For Blood Establishments, PE 005-3 2007

Definitions are described in IBTS/QA/LIST/0002.

10 ATTACHMENTS

10.1 Quality Policy
10.2 Authorisations/ Accreditations
10.3 IBTS Organisation Chart

QUALITY POLICY

The IBTS is committed to providing the following to all its users, donors, patients, hospital scientific and clinical staff the highest quality:

- blood and tissue products
- diagnostic and distribution services
- consultative services

The Quality Policy is implemented by the following:

- Implementation of a quality management system, the purpose of which is to continuously improve the quality of the products and services provided
- Setting quality objectives and plans to implement the quality policy
- Ensuring that all IBTS staff is familiar with the quality management system to ensure user satisfaction
- Upholding professional values and good professional practice
- Complying with all pertinent legislation

Signed_____ **Date**_____

Director of Quality and Compliance

IBTS Authorisations Held

Business Area	Authorisations/ Accreditations	IBTS Doc Ref.
Blood	Blood Establishment (Authorisation No. BE-002) under the terms of S.I. No. 360 of 2005.	IBTS/QA/AUTH/0001
Tissue	Tissue Establishment (Authorisation No. TE-012) under the terms of S.I. No. 158 of 2006.	IBTS/QA/AUTH/0002
	Manufacturing Authorisation Holder (Authorisation No.M11514 /00001) in accordance with 2001/83/EC and under the terms of the Medicinal Products (Control of Manufacture) Regulations 2007 to 2013 and S.I.No. 539 of 2007.	IBTS/QA/AUTH/0003
GDP	Wholesaler at NBC (Wholesale Distribution Authorisation No. W00011/00001) in accordance with 2001/83/EC transposed into the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013 and S.I. No. 538 of 2007.	IBTS/QA/AUTH/0004
	Wholesaler at MRTC (Wholesale Distribution Authorisation No. W00011/ 00002) in accordance with 2001/83/EC transposed into the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013 and S.I. No. 538 of 2007.	

IBTS Organisation Chart