Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Change Orders

Changes as described on Change Order:	Change Order No.

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TITLE: IBTS RED CELL IMMUNOHAEMATOLOGY LABORATORY MANUAL

Change Description:
Create new IBTS/RCI/LM/XXXX and IBTS/RCI/CM/XXXX. Expire IBTS/DIAG/QM/0001 and IBTS/RCI/UG/0001.
1. New laboratory manual for RCI lab to meet requirements of ISO15189. This new lab manual will replace the previous laboratory quality manual ref IBTS/DIAG/QM/0001. The new laboratory manual is a complete re-write and will reference the IBTS quality manual ref IBTS/QA/QM/0001 for general IBTS quality system requirements. The laboratory manual to include Quality Policy, Introduction to Lab functions, Quality Objectives, Scope, Regulatory Requirements, Authorisations and Accreditations, Organisation structure (RCI), Responsibilities, Standards Compliance ISO 15189 – Management Requirements, ISO 15189-Technical Requirements, Traceability and Haemovigilance

Reason for Change:
1. Follow on from development of IBTS quality manual as per document hierarchy structure as set out in CC 002/21/IBTS. This is also an implementation step for INAB accreditation for RCI as per CC 393/19/IBTS

Change order No.:
IBTS/CO/0189/21

Referenced Documents

BT – 0007	IBTS/QA/QM/0001	IBTS/RCI/SOP/0003
BT – 0345	IBTS/QA/SOP/0006	IBTS/RCI/SOP/0013
IBTS/ADM/POL/0001	IBTS/QA/SOP/0061	IBTS/RCI/SOP/0017
IBTS/ADM/SOP/0001	IBTS/QA/SOP/0062	IBTS/RCI/SOP/0028
IBTS/ADM/SOP/0002	IBTS/QA/SOP/0063	IBTS/RCI/SOP/0029
IBTS/ADM/SOP/0003	IBTS/QA/SOP/0068	IBTS/RCI/SOP/0030
IBTS/DP/POL/0001	IBTS/QA/SOP/0071	IBTS/RCI/SOP/0047
IBTS/DP/POL/0002	IBTS/QA/SOP/0076	IBTS/RCI/SOP/0050
IBTS/DP/POL/0018	IBTS/QA/SOP/0143	IBTS/RCI/SOP/0061
IBTS/DP/SOP/0006	IBTS/QA/SOP/0156	IBTS/RCI/SOP/0063
IBTS/DSP/SOP/0051	IBTS/QA/SS/0453	IBTS/RCI/SOP/0064
IBTS/FAC/SOP/0302	IBTS/QA/STD/0001	IBTS/RCI/SOP/0065
IBTS/FAC/SOP/0306	IBTS/QA/STD/0002	IBTS/RCI/SOP/0066
IBTS/FAC/SOP/0318	IBTS/QA/STD/0008	IBTS/RCI/SOP/0070
IBTS/FAC/SOP/0328	IBTS/QA/STD/0015	IBTS/RCI/SOP/0074
IBTS/FAC/SOP/0329	IBTS/QA/STD/0024	IBTS/RCI/SOP/0076
IBTS/FAC/SOP/0343	IBTS/QA/STD/0027	IBTS/REES/SOP/0001
IBTS/FAC/SOP/0348	IBTS/QA/STD/0028	IBTS/RR/BCP/0003
IBTS/IT/POL/0015	IBTS/QA/STD/0032	IBTS/RR/BCP/0004
IBTS/LABPT/UG/0001	IBTS/QA/STD/0035	IBTS/RR/POL/0002

IBTS/MED/POL/0009	IBTS/QA/VMP/0001	IBTS/VAL/RA/0070
IBTS/MM/SOP/0009	IBTS/QAV/SOP/0002	IBTS/VAL/SOP/0006
IBTS/QA/FORM/0004	IBTS/RCI/CM/0001	IBTS/VAL/SOP/0008
IBTS/QA/POL/0001	IBTS/RCI/LIST/0001	IBTS/VAL/SOP/0009
IBTS/QA/POL/0002	IBTS/RCI/LIST/0002	IBTS/VAL/SOP/0012
IBTS/QA/POL/0003	IBTS/RCI/SOP/0001	EHS/1000-0705/2007
IBTS/QA/POL/0007	IBTS/RCI/SOP/0002	

SmartSolve Roles

ISO SQS NBC	RCI MS NBC	QA THOD IBTS
LABS TMS NBC	RCI REAG SMS NBC	QC RAM IBTS
LM HT IBTS	RCI SMS NBC	TDOQ
MED CON IH NBC	RCI THOD NBC	
RCI LA NBC	QA BVO IBTS	

Training Type
Read only for all roles

SmartSolve Document Category

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

TABLE OF CONTENTS

1 QUALITY POLICY

The IBTS quality policy is described in the IBTS Quality Manual ref. *IBTS/QA/QM/0001*.

2 INTRODUCTION

This Red Cell Immunohaematology (RCI) Laboratory Manual and Policy should be read in conjunction with the Irish Blood Transfusion Service (IBTS) Quality Manual, *IBTS/QA/QM/0001*

The RCI Laboratory provides Red Cell Immunohaematology and Antenatal services for hospitals nationwide. The services provided by the RCI Laboratory include:

- ABO/Rh typing, this includes all blood group anomalies.
- Provision of crossmatched blood for patients with complex antibodies and for hospitals without Blood Transfusion Laboratories.
- Investigation of red cell antibodies including serologically complex cases.
- Investigation of Haemolytic Transfusion Reactions.
- Investigation of patient's with positive direct antiglobulin tests.
- Investigation of Autoimmune Haemolytic Anaemia.
- Investigation of monoclonal antibody interference
- Investigation of Haemolytic Disease of the Fetus and Newborn (HDFN).
- Identification of pregnancies at risk of HDFN by Antenatal Screening (antibody quantitation and / or antibody as appropriate
- Provision of suitable blood at delivery for both mother and baby for at risk pregnancies.
- Provision of scientific advice to hospital colleagues.
- Extended phenotyping for transfusion dependant patients and for patiens with complex red cell antibodies.
- Phenotyping of donor red cells and provision of phenotyped blood when not in stock.
- Clinical and scientific advice to hospital colleagues.
- Importation of rare blood / blood products for named patients.
- Emergency out of hours on-call service

The NBC RCI laboratory also provides an on call reference service for emergency complex investigations.

The laboratory receives aliquots of rare reference red cells from the Serum Cells and Rare Fluids (SCARF) and the UK red cell exchange programme for use in complex serological investigations. Liquid/frozen donations may be imported from International Donor Registries / Frozen banks for patients with extremely rare antibodies, where suitable donations are unable to be sourced in Ireland.

The laboratory complies with S1 547 of 2006 incorporating Articles 14 and 15 of Directive 98/ 2002/EC (Traceability Requirements, Notification of SAR/E). The laboratory is committed to obtaining the International Standard ISO 15189.

The laboratory operates to internal policies and procedures for all activities as defined by the IBTS Quality Management System. This manual is a controlled document as part of that System. All red cell referral & compatibility services undergo continuous review through quality assurance and audit activities.

IBTS laboratory management is committed to the provision of a full and effective service. To this end it ensures:

- Optimum staff recruitment, training, development and retention at all levels.
- Procurement, validation and maintenance of appropriate equipment /resources.
- Maintaining sample integrity and thereby the correct performance of laboratory examinations.
- Use of examination procedures that are fit for purpose and ensure the highest achievable quality.
- Timely, confidential, accurate and clinically useful reporting of examination results.
- Assessment of customer satisfaction, in addition to internal audit and external quality assessment.
- Notification to customers of significant changes to IBTS laboratory processes/procedures where the results or their interpretation could be significantly different, prior to implementation.

3 QUALITY OBJECTIVES

The following are the objectives of the IBTS RCI Laboratory Manual:

- To define and develop the Quality System associated with RCI Laboratory's activities to comply with regulatory requirement.
- To define the Regulatory Requirements to which the IBTS RCI Laboratory must operate.
- To define the IBTS RCI Laboratory Organisational Structure with respect to Quality Management System and Regulatory Requirements.
- To define the roles / responsibilities of the IBTS RCI Laboratory Personnel associated with the Quality Management System.
- To define the roles / responsibilities of the IBTS RCI Laboratory Personnel associated with the approval of this document.
- To define the IBTS RCI Laboratory Quality System as per the Irish Blood Transfusion Service (IBTS) Quality Manual.

4 SCOPE

The scope of this manual covers the IBTS RCI Laboratory's activities within the IBTS. This includes the provision of blood for Patients, RCI Laboratory Services including, routine blood transfusion testing (blood grouping, red cell phenotyping, antibody investigation, compatibility testing), reference serological investigations, antibody quantitation, antibody titration, investigation of monoclonal antibody interference, clinical interpretation of results where required, and an advisory service.

It has been compiled to meet the regulatory requirements outlined in section 5 of this document.

This Manual provides two functions, it describes the Quality management System for the benefit of the RCI laboratory's own management and staff and it provides information for customers, users and inspection/accreditation bodies.

5 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 products and amending Directive 2001/83/EC".
- EU Directive 2004/33/EC Annex IV titled "Storage, Transport and Distribution Conditions for Blood and Blood Products".
- SI 360 / 05 - European Communities (Quality and Safety of Human Blood and Blood Products) Regulations 2005. This is the statutory instrument which adapts the EU Directives as defined above Into Irish law.
- Traceability SI 547/06 - Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC".
- AML-BB current version titled "Minimum Requirements for Diagnostics Laboratory Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Blood Directive 2002/98/EU.
- 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".
- 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".
- ISO 15189:2012 - International Standard ~ Medical Laboratories – Particular requirement for Quality and Competence.
- INAB (Irish National Accreditation Board) applicable Policies and Procedures available on https://www.inab.ie/documents-forms/

6 AUTHORISATION AND ACCREDITION

The RCI Laboratory is currently in the process of applying for ISO1589 Accreditation. The IBTS is authorised for testing as part of the Blood Establishment authorisation issued by the HPRA.

7 ORGANISATION STRUCTURE

The Organisation Structure of the IBTS is outlined in *IBTS/QA/QM/0001*.

The Organisation Structure for the IBTS RCI Laboratory is outlined in **Attachment 15.1**.

8 RESPONSIBILITIES

The following table indicates the general roles, responsibilities and reporting structure within the RCI Laboratory. The IBTS organisational roles and responsibilities are listed in *IBTS/QA/QM/0001*. Deputies for all key functions have also been identified below. Specific operational roles and responsibilities are detailed in associated procedures. The following table details responsibilities by task:

Task No.	Description of Responsibility	Responsible
a.	Provide advice on choice of test, use of Laboratory services and interpretation of Laboratory results or data.	Consultant Haematologist / Director of RCI Laboratory Chief Medical Scientist Senior Medical Scientists
b.	Serve as an active member of the medical staff for the Organisation	Consultant Haematologists Specialist Medical registrars (Blood Transfusion)
c.	Relate and function effectively with: 1. Irish National Accreditation Board (INAB) / Health Products Regulatory Authority Board (HPRA) 2. Chief Executive 3. The other departments within the Organisation. 4. The patient population served 5. National Haemovigilance Office (NHO)	1. Quality Compliance & Regulatory Affairs Manager 2.Laboratory Director 3. & 4. Consultant Haematologist / Director of RCI Laboratory & Chief Medical Scientist 5. Biovigilance Officer
d.	Define, implement and monitor standards of performance and quality improvements of the medical Laboratory service or services.	RCI Laboratory Senior Management Team
e.	Implement the quality management system	Consultant Haematologist / Director of RCI Laboratory Chief Medical Scientist Senior Medical Scientists
f.	Monitor all work performed in the Laboratory to ensure reliable data is being generated and reported (Internal QC and EQA).	RCI Laboratory Senior Management Team
g.	Ensure personnel performing Laboratory tasks are suitably qualified, adequately trained and have the required experience.	Chief Medical Scientist Senior Medical Scientist (Responsible for Training)
h.	Plan, set goals, develop and allocate resources appropriate to the medical environment.	RCI Laboratory Senior Management Team
i.	Provide effective and efficient administration of the medical laboratory services, including budget planning and control with responsible financial management.	Chief Medical Scientist
j.	Provide educational programmes for the medical laboratory staff and ensuring participation in education programmes provided by the Organisation.	Consultant Haematologist / Director of RCI Laboratory Chief Medical Scientist
k.	Plan and direct research and development performed in the Laboratory (if applicable).	Consultant Haematologist / Director of RCI Laboratory Chief Medical Scientist Senior Medical Scientist

l.	Select and monitor all referral laboratories for quality of service.	Consultant Haematologist / Director of RCI Laboratory Chief Medical Scientist
m.	Implement a safe Laboratory environment in compliance with legal requirements, IBTS policy and Laboratory department safety procedures.	Chief Medical Scientist
n.	Address any complaint, request or suggestion from the customers of Laboratory services.	Consultant Haematologist / Laboratory Director Chief Medical Scientist / Quality Manager
o.	Ensure good staff morale.	RCI Laboratory Senior Management Team
p.	Ensuring requirements of EU Directive 2002/98/EC are met	Chief Executive Director of Quality and Compliance Quality Manager NBC Consultant Haematologist / Laboratory Director Chief Medical Scientist

The following table details the responsibilities by role.

Role	Role Description	Responsibility within the QMS	Delegation
Consultant Haematologist/ Director of RCI Lab	Clinical and administrative advice, management and co-ordination of the Laboratory Services	Responsibility and authority for all medical policies relevant to RCI laboratory. Advise on resources and promotes an environment that supports the development, implementation and ongoing workings of the Quality Management System in the RCI Lab. Reports to Medical and Scientific Director.	Consultant Haematologist /SpMO
Head of Testing	Provide oversight of the scientific, technical and management of the laboratory services	Provide oversight of the laboratory including regulatory compliance, accreditation and quality control, resource management, safety and contingency planning, performance management, strategic planning and implementation and continuous improvement.	Chief Medical Scientist
Chief Medical Scientist	Manages and oversees the running of the RCI Lab	Responsible for all technical aspects of Immunohaematological diagnostic testing and services. Development and implementation of the Quality System. Reports to Laboratory Director and Head of Testing.	Senior Medical Scientist

Director of Quality and Compliance	Responsible for the Quality Management System IBTS	Develops, implements and oversees the Quality Management System. Reports to the CE	Quality Manager
Senior Medical Scientists	Supervises day to day work-load in RCI Laboratory	Routine/complex testing in the RCI Laboratory. Provides advice to Medical Scientists. Reports to Chief Medical Scientist.	Senior / Medical Scientist
Medical Scientists	Performs day to day work-load in RCI Laboratory	Routine/complex testing in the RCI Laboratory / adhere to quality system in place. Reports to Chief Medical Scientist	Medical Scientist
Medical Laboratory Assistant	Provides laboratory assistance in the RCI Laboratory	Sample registration, Document retrieval, filing and charging. Sample discard. Reports to Chief Medical Scientist.	Medical Scientist
Laboratory Administration	Provide clerical support to the RCI Lab	Provide clerical support to the QMS	Laboratory Administration

9 RCI MANUAL

The policies of the IBTS RCI Laboratory are outlined within this Manual.

With reference to *IBTS/QA/QM/0001*, this outlines the policies for the RCI Laboratory's activity within the IBTS. The purpose of this document is to define in clear terms, the policies, guidelines, practices and procedures that control the effective delivery of the services provided as it relates to the RCI Laboratory. It has been developed under the authorisation of the Chief Medical Scientist and Consultant Haematologist / Director of RCI Laboratory.
This Manual is controlled as per *IBTS/QA/POL/0002*. It is authorised by the Responsible Person, Director of Quality and Compliance. It is reviewed every two years or as required due to a significant change.

All RCI Laboratory personnel are instructed on the use and application of the laboratory Manual and all associated documentation and of the requirements for their implementation.

10 STANDARDS COMPLIANCE ISO 15189 – STANDARD 4: MANAGEMENT REQUIREMENTS

This section is described as arranged in the current version of ISO 15189.

4.1 Organization and Management Responsibility

4.1.1 Organisation

4.1.1.1 General

This Manual describes the RCI Laboratory with respect to the IBTS Quality Management system which is included in the high level document, *IBTS/QA/QM/0001*. Throughout the text there are references to the following:

- ISO 15189 (ISO)
- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting 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
- Statutory Instrument S.I. No. 360 of 2005 European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005

The sections of the Quality Manual are arranged so that they equate with the ISO 15189 (2012) standards, with reference to the EU Directives and SI, as applicable. Under the title of each standard there is a brief description of the way in which the RCI Laboratory seeks to comply with the particular standard. References are given to appropriate procedures throughout the manual.

4.1.1.2 Legal Entity

The IBTS is legally identifiable under S.I. No. 22 of 2000
The Blood Transfusion Service Board (Establishment) Order, 1965 (Amendment) Order, 2000. The RCI Laboratory forms part of the IBTS as described in *IBTS/QA/QM/0001* and is identifiable as:

The IBTS Red Cell Immunohaematology Laboratory
Address:
National Blood Centre
James Street
D08 NH5R Dublin 8
Telephone: 01 4322972 / 01 4322973
Fax: 01 4322709

4.1.1.3 Ethical Conduct

The IBTS has processes in place to ensure the following:

a) There is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity
b) Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work
c) Where potential conflicts in competing interests may exist, they shall be openly and appropriately declared
d) There are appropriate procedures to ensure that staff treat human samples according to relevant legal requirements
e) Confidentiality of information is maintained at all times

Refer to IBTS HR policies and procedures on employee code of conduct.

4.1.1.4 Laboratory Director

The Director of the RCI Laboratory is a Consultant Haematologist, with the necessary professional qualifications, training, competence and delegated responsibility for the services.
The responsibilities of the Laboratory Director include professional, scientific, consultative and advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory. The Laboratory Director ensures that there is a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.
Contingency planning in the IBTS is managed by the Risk and Resilience Manager with reference to *IBTS/RR/BCP/0003* and *IBTS/RR/BCP/0004.*

The Laboratory Director (and appointees for delegated duties) has the necessary competence, authority and resources in order to fulfill the requirements of this International Standard.

The RCI Laboratory management team consists of the following:

- Consultant Haematologist (Laboratory Director)
- Head of Testing
- Chief Medical Scientist

4.1.2 Management and Responsibility:

4.1.2.1 Management Commitment

Refer to *IBTS/QA/QM/0001.*

The Quality Policy is displayed within the RCI Laboratory.

4.1.2.2 Needs of Users

RCI Laboratory Management ensures that services, including appropriate advisory and interpretative services, meet the needs of patients and those using the service. (Refer to 4.4 and 4.14.3).

4.1.2.3 Quality Policy

The RCI management team will ensure the laboratory complies with the IBTS Quality Policy laid out in *IBTS/QA/QM/0001*.
In addition the RCI Laboratory will comply with the standards set by ISO 15189, AML-BB, S.I. No. 360 of 2005 European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 and EU Directive 2002/98/EC (setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components) for the services and tests defined in *IBTS/RCI/CM/0001* and is committed to:

- Staff recruitment, training and development at all levels to provide an effective and efficient service to its users.
- Providing and managing resources to ensure that all examinations are processed to produce the highest quality results possible.
- Reporting results in ways, which are timely, confidential, accurate and are supported by clinical advice and interpretation when required,
- Implementation of Internal Quality Control, External Quality Assessment, Audit and Assessment of Customer Satisfaction to continuously improve the quality of the service
- Compliance with relevant environmental legislation.
- Adherence to appropriate technical and professional standards.

Management and staff are committed to creating a quality culture within the Department by continuously improving our services based on the results of performance through data review, internal quality audits, equipment maintenance, Quality Control programmes and the assessment of customers' needs

4.1.2.4 Quality Objectives and Planning

RCI Laboratory Management establishes quality objectives, including those needed to meet the needs and requirements of the customers of the service, at relevant function and levels within the organisation. These quality objectives are measurable and consistent with the Quality Policy. Refer to *IBTS/RCI/SOP/0066.*

The IBTS Quality Department ensures the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
Refer to *IBTS/QA/SOP/0006*

4.1.2.5 Responsibility, Authority and Interrelationships

RCI Laboratory management ensures that responsibilities, authorities and interrelationships are defined, documented and communicated within the Department. This includes the appointment of persons responsible for each function and appointment of deputies for key managerial and technical personnel.

All staff are responsible for ensuring compliance with both the EU Blood Directives and ISO 15189, including the Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification Of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC (AML-BB) (IBTS ref *IBTS/QA/STD/0028)*, in that Quality is everyone's responsibility.

The organisational chart, defining the Management structure of the Department, is fundamental to ensuring the Quality Management System is adequate in design, implementation, maintenance and continuous improvement.

4.1.2.5.1 Organisational Charts

Refer to *IBTS/QA/QM/0001* for organisation chart
Refer to RCI org chart (Attachment 15.1)

4.1.2.5.2 Responsibilities

Laboratory Director:
Refer to section 4.1.1.4

Director of Quality and Compliance
Refer to section 4.1.2.7

Head of Testing
The Head of Testing reports directly to the Medical & Scientific Director. This person has a strategic approach to the development of the service that embraces continuous quality improvement, technological development and the management of the changes necessary to achieve IBTS objectives.

Chief Medical Scientist
The Chief Medical Scientist manages and over sees the RCI laboratory. They are responsible for all technical aspects of Immunohaematological diagnostic testing and services. Reports to the Laboratory Director and Head of Testing as per the organisation chart in Attachment 15.1

Senior Medical Scientists:
The duties of the Senior Medical Scientist are as outlined for the Medical Scientist but with additional responsibilities including supervision of work carried out in the laboratory; ensuring compliance with set quality standards, participation in senior staff meetings to co-ordinate the day-to-day running of the laboratory.

Medical Scientists:
The duties of the Medical Scientist are to provide diagnostic services and participate in the routine work of the department. The Medical Scientist is responsible for the processing of specimens from receipt in the laboratory to issuing of the final report. They are also required to participate in internal and external quality control programmes and proficiency tests. He/she is required to maintain a high standard of service and ensure safe systems of work are maintained in accordance with good practice and appropriate legislation. The Medical Scientist must participate in staff training and departmental meetings ensure requests, specimens and reports are treated according to departmental protocol. He/she must keep abreast of professional developments, research and developments, especially in relation to the responsibilities described. He/she must maintain professional and technical competence and awareness by continued professional development and participate, as required, in the maintenance of personnel policy. The Medical Scientist must also assist in the introduction of new technologies, laboratory developments and services into the department.

Laboratory Aides
The duties of the Laboratory Aide are to assist in providing a diagnostic service and to assist with the routine work of the laboratory.

Laboratory Administrator
Clerical support is available from the NBC Laboratory Administrator and designee.

Biovigilance Officer
The IBTS Biovigilance Officer is responsible for the surveillance of blood from its collection to the follow-up of recipients, to collect and assess information on unexpected or undesirable effects resulting from the use of blood products and to prevent their occurrence or recurrence. This

includes the tracing of all blood products and reporting of any adverse reactions or events.

Director of Quality and Compliance

The DoQ&C has delegated responsibility and authority to

a) ensure that processes needed for the quality management system are established, implemented, and maintained;
b) report to RCI management, at the level at which decisions are made on RCI policy, objectives, and resources, on the performance of the quality management system and any need for improvement;
c) ensure the promotion of awareness of customers needs and requirements.

4.1.2.6 Communication

Lines of communication are cross-functional and open in the RCI Laboratory. Communication between staff and within the RCI laboratory occurs via e-mail, open discussion, departmental meetings, etc. (Also refer to 4.14.4). The effectiveness of the RCI laboratory is communicated during management review meetings, organisational meetings, posting of management review meeting minutes, customer satisfaction surveys, and internal audit results.

All formal meetings are documented.

Refer to *IBTS/QA/FORM/0004 and IBTS/RCI/SOP/0066.*

Annual Management Review

Refer to section 4.15

4.2 Quality Management System

The IBTS Quality Management system is described in *IBTS/QA/QM/0001*.

4.2.1 General Requirements

The IBTS Quality Management System is defined by the procedures it operates to control processes, which meet the defined policies. The IBTS RCI Laboratory ensures that the IBTS Quality Manual and all associated documented policies and procedures are understood and implemented by all relevant personnel.

4.2.2 Documentation Requirements

4.2.2.1 General

The quality management system documentation relevant to the RCI department includes;

a) The IBTS Quality Manual, *IBTS/QA/QM/0001* (Refer to 4.2.2.2)
b) This RCI Laboratory Manual including the RCI Quality Policy and specific quality objectives (Refer to 4.1.2.3 and 4.1.2.4).
c) Quality Assurance policies and associated procedures *(IBTS/QA/POL/0001, IBTS/QA/POL/0002, IBTS/QA/POL/0003 & IBTS/QA/POL/0007*)
d) Document and Record Policies and Procedures (*IBTS/QA/POL/0002, IBTS/DP/POL/0018, IBTS/QA/SOP/0156*) (Refer to 4.13)
e) Copies of applicable regulations, standards and other normative documents. (*IBTS/QA/STD/0001, IBTS/QA/STD/0002, IBTS/QA/STD/0008, IBTS/QA/STD/0015, IBTS/QA/STD/0024, IBTS/QA/STD/0027, IBTS/QA/STD/0028, IBTS/QA/STD/0032, IBTS/QA/STD/0035*)
   All documentation is available or referenced electronically on SmartSolve.

4.2.2.2 Quality Manuals

1. *IBTS/QA/QM/0001,* which is available electronically to all staff on SmartSolve, defines and describes the quality management system of the IBTS.
2. This RCI Laboratory Manual describes;
   a) The RCI Quality Policy (Refer to section 4.1.2.3)
   b) a description of the scope of the quality management system relevant to RCI (Refer to section 3)
   c) a presentation of the organization and management structure of the RCI laboratory and its place in the IBTS (Refer to section 4.1.2.5.1)
   d) a description of the roles and responsibilities of RCI management (including the Laboratory Director (refer to section 4.1.1.4) and Director of Quality & Compliance (refer to section 4.1.2.7)) for ensuring compliance with this International Standard; (Refer to section 4.1.2.5.2)
   e) a description of the structure and relationships of the documentation used in the quality management system with reference to RCI; (Refer to section 4.2.2.2.1)
   f) The documented policies established for the quality management system and reference to the managerial and technical activities that support them in the RCI Laboratory.
   g) The hierarchy of the documentation system is described in *IBTS/QA/QM/0001*.

4.3 Document Control

The use of SmartSolve fulfils this standard for both internal and external documents. The master copy is the electronic copy. Records are maintained

according to the requirements given in 4.13 (Control of Records). Document control is described fully in *IBTS/QA/QM/0001*.

4.4 Service Agreements

4.4.1 Establishment of Service Agreements

Contractual arrangements between the RCI Laboratory and its users (Customers) including Clinicians are defined by: (a) The SLAs (Service Level Agreements) which are agreed by the IBTS and their customers (Hospitals, Hospital Laboratories) and (b) the RCI Laboratory Request Forms which are used to requisition the diagnostic testing services of the Laboratory (BT - 0007 and BT - 0345).

The services provided by the RCI Laboratory are described in the RCI Customer Manual. Refer to *IBTS/RCI/CM/0001*.

The current list of customers (Hospital Blood Bank) is recorded and maintained in *IBTS/RCI/CM/0001*. Approval and establishment of new customers is carried out according to *IBTS/DSP/SOP/0051*.

Only requests on the official Request Forms (*BT - 0007* and *BT - 0345*) are accepted. The acceptance of a contracted test is based on the incoming inspection process as per *IBTS/RCI/CM/0001* and *IBTS/RCI/SOP/0003*. This covers labelling and identification of the sample bottle and request form. If the incoming inspection process fails, the customer is informed by phone and a repeat specimen to meet the RCI laboratory requirements may be requested. *Refer to IBTS/RCI/CM/0001*.

In the RCI Laboratory, each request accepted for examination is considered an agreement to provide medical laboratory services and takes into account the request, the examination and the report. The request form specifies the information needed to ensure appropriate examination and result interpretation.

All rejected requests are logged as invalid samples as per *IBTS/RCI/SOP/0003*. The requesting hospital or clinician is informed.

Where the RCI laboratory has entered into a contract to provide medical laboratory services to a hospital, a Service Level Agreement is established. *Refer to IBTS/ADM/POL/0001*.

Requirements, including the methods to be used are adequately defined, documented and understood by both the RCI laboratory and the customer of the Service.
The RCI laboratory has suitable physical resources and adequate numbers of personnel, who have the required qualifications, expertise and relevant training necessary to perform the required examinations.
The RCI laboratory provides access to the clinical advisory services of

a Consultant haematologist to all customers of the RCI Laboratory services.
Appropriate procedures selected are able to meet the contractual requirements and clinical needs of the customer.

Customers e.g. Hospitals and clinicians, are informed of any deviations from the contracted Request for tests. They are also informed of any deviations to the overall Service Level Agreement. This may include the following:

- Changes to the supply of blood/blood components as per the Product Master File.
- Changes in services already agreed between the two parties, outlined in *IBTS/RCI/CM/0001*
- Changes in responsibilities with regard to traceability of units issued from the IBTS.
- Changes in requirements for closing out investigations into incident reports and complaints.
- Changes in fees and charges.
- Terminations of agreements.

Reference shall be made to any referral laboratories, to which the RCI Laboratory refer specimens.

4.4.2 Review of Service Agreements

Records of reviews including any significant changes and pertinent discussions are maintained (see 4.13.2 of this Manual).

The IBTS Consultant Haematologist/Laboratory Director attend Hospital Transfusion Committees where invited and issues of IBTS service and policy within the contractual agreement are reviewed.

4.5 Examination by Referral Laboratories

4.5.1 Selecting and Evaluating Referral Laboratories and Consultants

Referral laboratories are used when the laboratory does not provide the examination requested (i.e. supplementary examinations) and when a back-up service is needed.

Selection and evaluation of referral laboratories and consultants is carried out according to *IBTS/QA/QM/0001* and *IBTS/ADM/POL/0001*.

The RCI laboratory operates an appropriate system for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions /clinical advice to the RCI Laboratory. Refer IBTS/RCI/CM/0001 for referral of specimens to external laboratories and for External laboratory testing.

RCI Laboratory Management with the advice of customers of the Laboratory Services where appropriate, are responsible for selecting and monitoring the quality of referral laboratories and consultants and ensuring that the referral laboratory or referral consultant is competent to perform the requested examinations.

The prerequisites of the referral laboratory are as follows:

- All referral tests are of acceptable quality.
- The laboratory normally performs the testing which they contract to undertake.
- The laboratory participates in external quality assessment schemes.
- The laboratories meet the needs of timeliness, quality and safety and in compliance with accreditation.

The RCI Laboratory maintains a list of all Referral Laboratories in *IBTS/RCI/CM/0001*. The name and address of the Referral Laboratory responsible for the examination result is available to the user of Laboratory Services. A duplicate of the Referral Laboratory / Diagnostics Laboratory report is retained in the patient investigation record and a further duplicate goes to the Hospital. The original report is filed with the appropriate 'File Number' in the Sample Referral register. Refer to *IBTS/RCI/CM/0001* for referral of specimens to external laboratories for external laboratory testing. *Refer also to IBTS/RCI/SOP/0013*

The RCI Laboratory is responsible for ensuring that referral laboratory examination results and findings are provided to the person making the request.
Refer to IBTS/RCI/CM/0001, IBTS/RCI/SOP/0013.

4.5.2 Provision of Examination Results

Referral letters that are issued directly to the Referring Laboratory are issued as per *IBTS/RCI/SOP/0013*.
The IBTS is responsible for ensuring that the examination results of the referral laboratory are provided to the requesting hospital.
Where the RCI Laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory, without alterations that could affect clinical interpretation.

The referring RCI Laboratory Director may elect to provide additional interpretative remarks to those, if any, of the referral Laboratory, in the context of the patient and the local medical environment. The author of such added remarks shall be clearly identified.

All Laboratory reports issued, including reports from testing carried out on site or at a referral laboratory are signed by the Chief Medical Scientist / Designee authorising the issue of the report. Reports containing a clinical recommendation or advisory note are also

authorised and signed by the Consultant Haematologist / Laboratory Director.

4.6 External Services and Supplies

The IBTS defines practice for the selection and use of purchased external services, equipment, reagents and consumables considered to be critical to the delivery of its service. *Refer to IBTS/ADM/SOP/0003*.

RCI selects and approves suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratories requirements. This evaluation includes the review of supplier performance, as per procedure *IBTS/ADM/SOP/0003*. Results of these evaluations are documented and feed into the Annual Management Review, Ref *IBTS/RCI/SOP/0066*. Suppliers consistently not meeting the laboratories requirements will be removed from the approved supplier's list.

A master list of approved critical suppliers of service and materials is maintained as per *IBTS/RCI/LIST/0002*.

4.7 Advisory Services

The RCI Laboratory operates a Clinical Advisory Service. RCI Management aims to ensure that Laboratory Services, including appropriate interpretation and advisory services are designed to meet the needs of patients and all clinical personnel responsible for patient care.
The Consultant Haematologist / Director of RCI Laboratory NBC / Chief Medical Scientist advise on all issues relating to Blood Transfusion and Haemovigilance and the use of Blood and Blood Products.
The Biovigilance Officer advises on Haemovigilance where required.
The Consultant Haematologist / Laboratory Director provide clinical advice.
Appropriate (qualified / experienced) RCI Laboratory Medical and Scientific staff provide advice to clinicians / customers on choice of examinations and use of services, including repeat frequency and type of sample required for testing in the RCI Laboratory. Refer to IBTS/RCI/CM/0001 Laboratory Tests and Services.
Where appropriate, interpretation of the results of examinations will be provided by the Consultant Haematologist / Laboratory Director / the Medical Scientist, as appropriate.

The RCI Laboratory is readily available to provide advisory services on the following:

- The evaluation and interpretation of results of laboratory examinations
- The suitability and adequacy of the sample for the investigation requested
- The precision and accuracy of methods employed in the laboratory
- The statistical significance of results and their relation to reference ranges
- The scientific basis and the clinical significance of the result
- The suitability of the requested procedure to solve the clinical problem in question
- Appropriate additional investigations

4.8 Resolution of Complaints

Complaints may be received from a number of sources, including:

- external customers/suppliers of the service,
- another department within the IBTS

Any complaints received are dealt with initially as per *IBTS/QA/SOP/0063.*

Complaints may also be made by the RCI Laboratory towards

- external customers/suppliers of the service *(Ref IBTS/ADM/SOP/0003)*
- another department within the IBTS *(Ref IBTS/QA/SOP/0068)*

Consideration of the findings forms part of the Annual Management & Quality Review to further improve the quality system.
Refer to IBTS/RCI/SOP/0066

The RCI laboratory documents and investigates all perceived or real grievances from Clinicians, Hospital laboratory staff, or other related parties pertaining to the RCI Laboratory. This includes complaints that are classified as Serious Adverse Reactions or Events and any issues concerning Traceability. The Chief/Designee of the RCI Laboratory performs an investigation and documents the results of their root cause analysis. A detailed description of the complaint is recorded on a complaint form, refer to *IBTS/QA/SOP/0063*. Each complaint is categorised (this is a standard categorisation) by the Quality Assurance Department. Based on the findings, the RCI Laboratory Chief Medical Scientist identifies suitable corrective and preventative actions in conjunction with any other relevant parties to prevent a recurrence of the issue. Corrective and Preventative Action (CAPA) taken is also documented. The RCI laboratory Chief Medical Scientist maintains a log of all complaints they are dealing with and on closure, they return the completed documentation to the Quality Assurance department. QA maintains a register of all the complaints. *Refer to IBTS/QA/SOP/0063.*

Review and Assessment of Customer Satisfaction

Customer satisfaction is assessed through periodic survey of customers, feedback received at Hospital Transfusion Committee meetings and processing of complaints. Customer complaints are reviewed at the RCI SMS Meeting, Laboratory Meetings and Annual Quality Review meeting.
Service Level Agreements
The IBTS enters into a Service Level Agreement (SLA) with all hospitals to which they supply blood/blood components and other services for patients of the hospitals. The SLA is subject to periodic review.
The objectives of the agreement include:

- The supply of blood / blood components in accordance with the Product Master File. The services provided including; blood grouping, crossmatching for named patients, antibody referral service, antibody quantification service, and such other services as agreed by the parties.
- The identification of the responsibilities of the IBTS and the said hospitals in the traceability of each unit issued from the IBTS and the need for a structure to deal with non-conforming issues.

- Notice of IBTS fees and charges; and the role of the IBTS and the said hospitals in the termination or amendment of the agreement.

Customer Complaints
The RCI Laboratory operates within the IBTS quality system incorporating blood components / services complaint defect procedures. *Ref IBTS/QA/SOP/0063*

The objectives of the complaints handling system requires that:

- All complaints are rapidly and effectively handled; and fully investigated.
- The appropriate corrective and preventative actions are taken to reduce the risk of repeated errors.
- The relevant information is recorded and reported to the Consultant Haematologist & Quality Manager as appropriate.
- The customer receives a letter from the Quality Assurance / Medical Department in response to the complaint.
- Customer confidence is maintained in the service.

Quality Management Review
The RCI Laboratory holds an annual quality review meeting which reports on all aspects of the RCI Laboratory services.

Customer Liaison
The RCI Laboratory performs yearly surveys of customer satisfaction and also holds an in IBTS User Symposia and present at the National Haemovigilance Office Conferences when requested. User issues are discussed and the IBTS inform their customers of new procedures and services at these events. The customer is also afforded the opportunity to give the IBTS feedback on the service being provided to them. The RCI Laboratory welcomes site visits to the laboratory by their customers.

Hospital Transfusion Committees
The IBTS Consultant Haematologist (designated nominee) / Chief Medical Scientist attend Hospital Transfusion Committees meetings, at hospitals where the laboratories provide hospital blood bank services; where issues of IBTS service and policy are discussed.

Continuous Improvement
The IBTS continually monitors the suitability and effectiveness of the quality program which is in place in the organisation, through the Quality Management System.

The Laboratories' Annual RCI Management and Quality Review is a key element of the continuous improvement process.
The Internal Auditing process is used to review continuous improvement. *Refer to IBTS/QA/SOP/0076 and IBTS/RCI/SOP/0070.* All complaints relating to the RCI laboratory service are reviewed at the RCI Laboratory and RCI SMS meetings and at the Annual RCI Laboratory Management Quality review meetings. *Refer to IBTS/RCI/SOP/0066.* They are categorised by the QA Manager in line with the IBTS Complaints procedure. *Refer to IBTS /QA/SOP/0063*. Minutes of all meetings are maintained. The effectiveness of the actions is evaluated through these meetings and through the Internal Auditing System.

Complaints are also reviewed by Quality Assurance on an ongoing basis. *Refer to IBTS/QA/SOP/0063.*

The RCI Laboratory holds annual User Symposia where customer issues are discussed and the IBTS inform their customers of new technology, new professional developments, procedures and services. This meeting also provides the customer with an opportunity to give the IBTS feedback on the service being provided to them.

Customer satisfaction is also assessed through a yearly survey of customers where the Quality and appropriateness of the Laboratory Service and its contribution to patient care is evaluated and monitored in an objective manner.

Customer feedback is also obtained through the Laboratory Director's participation in Hospital Transfusion Committee Meetings, reviewing of complaints and convening of RCI user symposia. This establishes that the service provided by the RCI Laboratory meets the needs and requirements of users.

It also presents the laboratory with the opportunity to become aware of changing clinical requirements and/or customer needs, thus improving the quality of service provided. Customer satisfaction surveys are used as a Quality indicator to measure customer satisfaction with the Laboratory Service. The use of surveys presents the opportunity to obtain both positive and negative feedback from clinicians and other service users.

Trending analysis is performed by the Chief Medical Scientist at regular intervals.

All complaints relating to the RCI laboratory service are reviewed at the Annual RCI Laboratory Management & Quality review meetings. *Refer to IBTS/RCI/SOP/0066.* They are categorised by the QA Manager in line with the IBTS Complaints procedure. Minutes of all meetings are maintained.

4.9 Identification and Control of Non-Conformances

The RCI Laboratory manages non conformances as per the IBTS Quality Incident reporting system described in *IBTS/QA/SOP/0068.*
Where any aspect of the RCI laboratory examinations does not conform to its own procedures, the following will occur,

a) The Chief of RCI /Designee is responsible for non-conformance resolution.
b) The immediate actions to be taken are defined and recorded in the incident report
c) The extent of the non conformance is determined.
d) Testing may be suspended until all issues pertinent to the non-conformance are investigated.
e) The medical significance of the non-conformance is considered and if appropriate, the requesting clinician informed.
f) Results already released are recalled if required.
g) The Chief/Designee will authorise resumption of testing if suspended.
h) Each non-conformance is documented as part of *IBTS/QA/SOP/0068,* records are reviewed at intervals by Laboratory management to detect trends and reduce/prevent further occurrences.

Quality Incident Reports are categorised to assist with review and trend analysis which is performed by the RCI Laboratory Chief Medical Scientist or designee at regular intervals. RCI Laboratory Management reviews the Quality incident reports at the monthly RCI Meetings, the RCI Laboratory Senior meetings and at the Quarterly and Annual RCI Management & Quality Review Meetings. Minutes of all meetings are maintained. *Refer to IBTS/RCI/SOP/0066.*

Following investigation / review of a non-conforming examination result and where it is found that it could recur or that there is doubt about the RCI Laboratory's compliance with its own policies or procedures as given in the quality manual, then troubleshooting, root cause analysis methods are used to identify, document and eliminate the root cause of this problem. This corrective action is promptly implemented. All supporting documentation is attached to the Quality Incident. Refer to *IBTS/QA/SOP/0068* and to Section 4.10 of this manual, 'Corrective Action'.

The RCI Laboratory defines and implements procedures for the release of results in the case of non-conformances, including the review of such results. These events are recorded. The Chief Medical Scientist / Designee, on the authorisation of the Consultant Haematologist / Director of RCI Laboratory release such results having recorded the non conforming event using *IBTS/QA/SOP/0068.*

4.10 Corrective Action

The RCI Laboratory manages corrective actions as per the IBTS Quality Incident reporting system described in *IBTS/QA/SOP/0068.*

Corrective actions may arise from non-conformances or activities which occur in many different areas and can be identified in many different ways including complaints (internal/external), quality control indications, instrument calibrations, checking of consumable materials, staff comments, reporting and certificate checking, management review, internal and external audits.

IBTS/QA/SOP/0068 ensures an investigative process to determine the cause of an incident is performed. The nature of the corrective action depends on the classification of the non-conformance and of its potential risk to the patient. Quality incidents that can cause or have the potential to cause harm are assigned an appropriate risk categorisation.. For any incidents affecting haemovigilance or traceability activities, the same corrective action and investigative process is applied. Corrective action is appropriate to the magnitude of the problem and commensurate with the possible risks. Serious Adverse Reactions and Serious Adverse Events are also reported to the appropriate authority (National Haemovigilance Office).

Any changes required to RCI Laboratory operational procedures resulting from corrective action investigations are documented and implemented as per *IBTS/QA/SOP/0006* and associated procedures.
RCI Laboratory management monitors the results of any corrective action taken, in order to ensure that they have been effective in resolving the identified issues. This is performed through the RCI Quality Management process as per *IBTS/RCI/SOP/0066.*

When the identification of a Quality Incident or the corrective action investigation casts doubt on compliance with policies and procedures or the Quality management System, RCI Laboratory Management ensures that appropriate areas of activity are audited in accordance with the Internal Auditing process, *IBTS/QA/SOP/0076* and *IBTS/RCI/SOP/0070.*

4.11 Preventative Action

The RCI Laboratory manages preventative actions as per the IBTS Quality Incident reporting system described in *IBTS/QA/SOP/0068* and IBTS Quality Management Review System *IBTS/QA/SOP/0062.*

Preventative Action is regarded as a pro-active process for identifying opportunities for improvement rather as a reaction to a problem. Preventative action, where appropriate, is identified through activities which occur in many different areas and can be identified in many different ways including staff suggestions, improvement activities, change controls, brain storming, meetings, complaints, non-conformances, quality control indications, instrument calibrations, checking of consumable materials, staff comments, reporting and certificate checking, management review, internal and external audits.

If potential areas for improvement are identified, a root cause analysis is performed to identify actions and controls.

Procedures for preventative action include the initiation of actions and controls to prevent the occurrence of non-conformities. The Annual Management Review process may determine preventative action as appropriate based on review of predefined activities as set down in the Annual Management Review Agenda.

RCI Laboratory Management ensures that an appropriate form of preventative action is implemented. Where preventive action is required an action plan will be developed, implemented and monitored to reduce the likelihood of reoccurrence and to take advantage of the opportunities for improvement. This procedure is also used for reporting any issues concerning traceability and for reporting Haemovigilance issues such as Serious Adverse Events.

The effectiveness of preventative actions will be monitored through the Auditing Process, (*IBTS/QA/SOP/0076, IBTS/RCI/SOP/0070*) and the RCI Management Review Process (*IBTS/RCI/SOP/0066*) to ensure that they have been effective in resolving the identified issues. Required improvements and potential sources of Quality Incidents, either technical or concerning the Quality Management System, are identified. If preventative action is required, action plans are developed, implemented, and monitored to reduce the likelihood of the occurrence of such quality incidents and to take advantage of the opportunities for improvement.

Preventive action may include some or all of the following:

- Review of operational procedures
- Analysis of data
- Trend analysis
- Risk analysis
- External Quality assurance

4.12 Continual Improvement

Continual quality improvement is an essential part of maintaining and improving the RCI laboratories services.

Continuous improvement is achieved throughout the Department in a number of different ways including:

- Change Control (*IBTS/QA/SOP/0006*)
- Biannual Document Review *(IBTS/QA/POL/0002)*
- Equipment Maintenance (*IBTS/QA/VMP/0006)*
- Monitoring of Turn around times (*IBTS/RCI/SOP/0076*)
- Management Review (*IBTS/RCI/SOP/0066*)
- Internal Audits/External Audits (*IBTS/QA/SOP/0076 & IBTS/RCI/SOP/0070*)
- Customer complaints or recommendations (*IBTS/QA/SOP/0063*
- Assessment of Customer Satisfaction (*IBTS/RCI/SOP/0066)*

- Assessment of Suppliers *(IBTS/ADM/SOP/0003)*
- Training (*IBTS/QA/POL/0007 & IBTS/RCI/SOP/0028)*
- Further education and Continual Professional Development (*L&D Strategy)*
- External Quality Assessment (EQA) reports (*IBTS/RCI/SOP/0061*)
- The Non-Conformance System : Incident Reports and Complaints (*IBTS/QA/SOP/0068* and *IBTS/QA/SOP/0063)*
- Risk Assessments (*IBTS/RR/POL/0002)*
- Laboratory meetings (*IBTS/RCI/SOP/0066)*

When the continual improvement programme identifies opportunities for improvement, RCI Management will address them regardless of where they occur. RCI Management communicates improvement plans and related goals to RCI staff.

4.13 Control of Records

The IBTS implements a procedure for the identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records, including those pertaining to Haemovigilance and Traceability activities. *Refer to IBTS/QA/POL/0002, IBTS/DP/POL/0002, IBTS/DP/POL/0018 and IBTS/RCI/SOP/0050.*

RCI records include but are not limited to the following:

a) Request forms
b) Examination results and reports
c) Instrument print outs
d) Examination procedures
e) RCI laboratory work-books and registers
f) Accession records
g) Calibration functions and conversion factors
h) Quality Control records
i) Complaints, Non Conformances and actions taken
j) Records of internal audits, external audits, regulatory inspections and assessments
k) External quality assessment records / inter laboratory comparison
l) Quality improvement and preventative action records
m) Instrument maintenance records, equipment event logs and internal/external calibration records
n) Risk management records
o) Lot number documentation, certificates of conformance, package inserts
p) Incident/accident records and actions taken
q) Staff training and competency records
r) Supplier selection and performance
s) Quality management review records including minutes of meetings

All quality and technical records are available for the Management Review (Refer to 4.15)

The method for record disposal is described in *IBTS/DP/SOP/0006*.

4.14 Evaluation and Audits

4.14.1 General

The laboratory plans and implements the internal audit processes and evaluation needed to:

a) Demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of customers and the laboratory;
b) ensure conformity to the quality management system;
c) Continually improve the effectiveness of the quality management system.

Refer to *IBTS/QA/SOP/0076* and *IBTS/RCI/SOP/0070*.

4.14.2 Periodic Review of Requests and Suitability of Procedures and Sample Requirements

Authorised personnel, who include the Chief Medical Scientist and the Consultant Haematologist, periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. Sample volume, collection device and preservative requirements for blood sample types are also periodically reviewed to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measured parameter.

4.14.3 Assessment of Customer Feedback

The Department obtains information relating to customer perception on whether the service has met the needs and requirements of its users. Records are kept of information collected and actions taken.
Refer to IBTS/RCI/SOP/0066.

4.14.4 Staff Suggestions

RCI Management encourages staff to make suggestions for the improvement of any aspect of the RCI service. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management are maintained.
Refer to IBTS/RCI/SOP/0066

4.14.5 Internal Audit

The audit programme takes into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits.

All elements of ISO 15189 managerial, technical and Haemovigilance / Traceability activities are audited annually as per the RCI Internal Audit Schedule. The internal audits shall progressively address these elements and emphasis areas critically important to patient care. Refer to *IBTS/QA/SOP/0076* and *IBTS/RCI/SOP/0070*.

The audit criteria, scope, frequency and methods are defined and documented in *IBTS/QA/SOP/0076* and *IBTS/RCI/SOP/0070*.

The selection of auditors and the performance of the audits ensures objectivity and impartiality of the audit process. Auditors are independent of the activity to be audited. All auditors are trained.

Personnel responsible for the area being audited, ensure that appropriate action is promptly undertaken when audit findings are identified. Corrective action is taken without undue delay to eliminate the causes of the detected findings, particularly those having clinically significance. (Refer to 4.10).

The results of internal audits are reviewed by RCI Laboratory Management and are submitted quarterly to Quality. Refer to *IBTS/QA/SOP/0076, IBTS/RCI/SOP/0066* and *IBTS/RCI/SOP/0071*.

4.14.6 Risk Management

The RCI Laboratory reviews the impact of work processes and potential failures on examination results as they affect patient safety, and will modify processes to reduce or eliminate the identified risks and document decisions and actions taken.

Quality risk management will be used to evaluate the laboratory processes to determine the potential impact on patient safety. Quality Risk Management is described in *IBTS/QA/QM/0001* and *IBTS/RR/POL/0002*.

The risk assessment of all tests, equipment and materials is performed as per *IBTS/VAL/SOP/0012* and *IBTS/VAL/RA/0070*.

4.14.7 Quality Indicators

The Department has established quality indicators to monitor and evaluate performance throughout critical aspects of processes.

The process of monitoring quality indicators is planned, and includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.

The Quality Indicators for the Department include the following:

Area	Indicator	Associated Documentation
RCI	• Internal Audits Completion • Audit findings-actions completed • Training completed • Document certification completed • Incident Reports • Customer complaints • Document Management- periodic reviews complete before expiry • Customer Satisfaction • Turnaround times • EQA performance • IQC performance • Number of unacceptable samples • Number of corrected reports	• *IBTS/RCI/SOP/0076* • *IBTS/RCI/SOP/0066* • *IBTS/QA/SOP/0062*
Biovigilance	• Traceability • SAE/SAR/Near Miss • Number of components issued • Number of units transfused • Number of recipients receiving transfusions • Number of units discarded • Number of units expired • Number of units returned	• *IBTS/QAV/SOP/0002* • *IBTS/RCI/SOP/0066* • *IBTS/RCI/SOP/0065*

4.14.8 Reviews by External Organisations

When reviews by external organisations indicate RCI Laboratory has non-conformances or potential non-conformances, the RCI Laboratory takes appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements. Records are kept of the reviews and of the corrective actions and preventive actions taken. (Refer to 4.13)
Refer to *IBTS/QA/QM/0001*.

4.15 Management Review

4.15.1 General

Management review constitutes an overview of the entire Department's quality system and is performed on an annual basis at the start of every year, to assess the overall effectiveness of the quality system and to establish objectives for the coming year. This review applies to laboratory services, clinical and advisory services and biovigilance and traceability activities within the RCI service. This overview reviews the continuing suitability of the RCI Laboratory and its effectiveness in support of patient care and the need to introduce any necessary changes or improvements. From the review, improvements to the system can be made.
Refer to *IBTS/RCI/SOP/0066.*

4.15.2 Review Input

The Agenda of the Management Review includes, but is not limited to the following:

a) the periodic review of requests, and suitability of procedures and sample requirements (Refer to 4.14.2),
b) assessment of user feedback (Refer to 4.14.3),
c) staff suggestions (Refer to 4.14.4),
d) internal audits (Refer to 4.14.5),
e) risk management (Refer to 4.14.6),
f) Quality indicator Performance (Refer to 4.14.7),
g) reviews by external organisations (Refer to 4.14.8),
h) results of participation in inter-laboratory comparison programmes (PT/EQA) (Refer to 5.6.3),
i) monitoring and resolution of complaints (Refer to 4.8),
j) performance of suppliers (Refer to 4.6),
k) identification and control of nonconformities (Refer to 4.9),
l) results of continual improvement (Refer to 4.12) including current status of corrective actions (Refer to 4.10) and preventive actions (refer to 4.11),
m) follow-up actions from previous management reviews,
n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;
o) Recommendations for improvement, including technical requirements.

Refer to *IBTS/RCI/SOP/0076* and *IBTS/RCI/SOP/0066*

4.15.3 Review Activities

The review analyses the input information for causes of non-conformances, trends and patterns that indicate process problems. This review includes assessing these opportunities for improvement and the need for changes to the RCI ISO Manual, including the quality policy and quality objectives.

The quality and appropriateness of the Department's contribution to patient care is, to the extent possible, also objectively evaluated.

4.15.4 Review Output

The output from the management review are incorporated into a record that documents any decisions made and actions taken during the review related to:

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of services to users,
c) Resource needs.

Findings and the actions that arise from management review are recorded and all RCI personnel are informed of these findings and the decisions made as a result of the review. Management ensure that arising actions are discharged within an appropriate and agreed-upon time.
Refer to *IBTS/RCI/SOP/0066.*

11 STANDARDS COMPLIANCE ISO 15189 – STANDARD 5: TECHNICAL REQUIREMENTS

5.1 Personnel

5.1.1 General

Refer to Attachment 15.1 for the Organisation Chart for the RCI Laboratory activities at the IBTS.

The Human Resources Department at the IBTS have in place Personnel / Recruitment Policies, Refer to the IBTS Human Resources Staff Manual accessible via IT network desktop and *IBTS/QA/QM/0001*.
Refer to Section 2.6.2 of this Manual for details pertaining to the Roles and Responsibilities of key positions in the RCI Laboratory and for designated deputies.
Written job descriptions are held on file by the HR department for all grades of personnel including:

- Consultant Haematologist, Director of RCI Laboratory, NBC
- Director of Quality and Compliance
- Chief Medical Scientist
- Senior Medical Scientist
- Basic Grade Medical Scientist
- Laboratory Aide

5.1.2 Personnel Qualifications

Personnel qualifications for each position are documented within job descriptions. The qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and are appropriate to the tasks performed.

The personnel making judgments with reference to examinations have the applicable theoretical and practical background and experience.

The Human Resources Department maintains records of the relevant educational and professional qualifications, training and experience, and competence of all personnel to include.

a) Certification or license.
b) References from previous employment.
   The Human Resources Department maintains references from previous employment.
c) Qualifications
d) Other Records Relating to Personal Health, including pre- employment.

Inclusion on the Specialist register is required for Consultant Haematologist and all doctors must be on the Irish Medical Register to practice medicine.

All Medical Laboratory Scientists are required to be eligible for acceptance by The Academy of Medical Laboratory Sciences and are state registered with CORU.

5.1.3 Job Descriptions

Each member of staff has a contract and job description prepared by the IBTS Human Resource Department. A copy of an employee's contract and job description are available through the Human Resources Department. (Refer to 4.1.2.5.2)

Job descriptions are in place which clearly defines the qualifications and duties of every position within the scope of this manual. Job descriptions are authorised by the Human Resources Department in conjunction with the Consultant Haematologist / Director of RCI Laboratory NBC, Head of Testing and / or Chief Medical Scientist as appropriate, and are reviewed, prior to advertising for staff.

5.1.4 Personnel Introduction to the Organisational Environment

All new employees attend on- boarding and induction within the IBTS which is described in the IBTS Human Resources Manual.

5.1.5 Training

Training is provided for all personnel which includes the following areas:

a) Quality Management System, *IBTS/QA/QM/0001*.
b) assigned work processes and procedures,
c) the applicable laboratory information system,
d) health and safety, refer to RCI departmental safety manual on Scannell,
e) Confidentiality of patient information, *IBTS/DP/POL/0001*.

Personnel that are undergoing training are supervised at all times.
The effectiveness of the training programme is periodically reviewed as per *IBTS/RCI/SOP/0066.*
Training of personnel is controlled by *IBTS/QA/POL/0007.*
The RCI Laboratory has individual training plans for each new member of staff.

5.1.6 Competence Assessment

The competency of each person to perform assigned task is assessed following training and periodically thereafter. Retraining and reassessment takes place when necessary.
Competency / Proficiency assessments are carried out as outlined in *IBTS/RCI/SOP/0028*.
Electronic training records are held on SmartSolve in the personal file of each employee.

Competency Evaluations / Proficiency Testing.

Competency assessment records are maintained for scientific staff, and are filed in their individual Training Folders.

5.1.7 Reviews of Staff Performance

In addition to the assessment of technical competence, the laboratory ensures that staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the customers and encourage productive working relationships.

5.1.8 Continuing Education and Professional Development

All members of staff are given the opportunity for further education and training in relation to the needs of the service and their professional development. All staff members are encouraged to demonstrate their on-going commitment to continuing education through the pursuit of further education and by keeping up to date with new technology. Funding may be provided for relevant courses and meetings as well as on-site and off-site training. This is captured yearly through the PD process and records of continuing education and achievements are maintained.

The effectiveness of the continuing education programme is periodically reviewed by laboratory management and by IBTS Learning and Development functions.
Scientific and Medical personnel attend National and International meetings and seminars and other professional meetings for continued professional development and records of these are maintained by the staff member.

5.1.9 Personnel Records

The Human Resources Department maintain personnel records for all members of staff. The information on these files is treated in the strictest of confidence at all times. In order to maintain these files accurately, one is required to notify the Human Resources Department of any changes in the relevant information. Additional records such as training and competency are maintained in SmartSolve and in the laboratory.

These records are readily available to relevant personnel and include (but are not limited) to:

a) educational and professional qualifications,
b) copy of certification or license, when applicable,
c) previous work experience,
d) job descriptions,
e) introduction of new staff to the working environment,
f) training in current job tasks,
g) competency assessments,
h) records of continuing education and achievements,
i) reviews of staff professional development,
j) reports of accidents and exposure to occupational hazards,
k) Immunisation status, when relevant to assigned duties.

5.2 Accommodation and Environment

5.2.1 General

The RCI Laboratory operates so that its workload can be performed without compromising the quality of work and safety of personnel or patient care services. The Consultant Haematologist/Director of RCI Laboratory NBC, Head of Testing, and Chief Medical Scientist ensure that suitable accommodation with adequate space and resources are provided for the RCI Laboratory and primary sample examination activities. This ensures that work can be performed without compromising the quality of work, the quality control procedures, the safety of personnel or the patient care services.

5.2.2 Laboratory and Office Facilities

The RCI Laboratory is designed such that there is clear segregation between clerical and laboratory areas resulting in efficiency of its operation. This also ensures the comfort of its occupants and minimises the risk of injury and occupational illness.

Employees and visitors are protected from recognized hazards, by ensuring that the following are in place:

- Adequate and appropriate Safety signage where there are potential hazards.
- Hazardous chemicals / gases etc are stored in suitable, clearly labelled storage facilities.
- Adequate and suitable personal protective equipment is available when required.
- Access to areas affecting the quality of examinations is controlled. The RCI Laboratory is within the GMP laboratory area on the 1st floor of the NBC which is swipe access controlled. Each new staff member receives a swipe identification card from Security on commencing employment with the IBTS.
- Medical information, patient samples, and laboratory resources are safeguarded from unauthorised access, (Refer to 5.2.2 (a), all computer systems are password protected.
- Facilities for examination allow for correct performance of examinations,
- Management recognises the value of good communication systems within the Department. This includes

    - Email is primarily used as a communication medium within the RCI Laboratory
    - RCI Laboratory Meetings
    - Senior Staff meeting
    - Annual Quality Management Review Meetings
    - Transfusion Committee Meetings
    - Customer Liaison Days
    - RCI User Group meetings
    - Laboratory register for samples
    - Notice board (for working arrangements and On Call Rotas, Daily tasks and Daily stock tasks)
    - Staff Suggestion board

5.2.3 Storage Facilities

Adequate storage areas are in place to ensure the continuing integrity of blood samples, supplies, reagents, consumables, documents, files, manuals, equipment, records and results. Refer to *IBTS/QA/QM/0001*.

5.2.4 Staff Facilities

All staff have access to facilities within the NBC to ensure personnel safety, comfort and hygiene as described in *IBTS/QA/QM/0001*.

5.2.5 Patient Sample Collection Facilities

Patient samples are not collected at the NBC facility but are referred to the RCI laboratory for testing from hospitals.

5.2.6 Facility Maintenance and Environmental Conditions

The RCI Laboratory design is suitable for the tasks carried out therein. The environments in which the examination / testing are performed are controlled so that results of testing performed are valid and not adversely affected in quality.

The laboratory facilities are designed and maintained to have;

- Adequate electrical supply
- Adequate lighting
- Adequate ventilation
- Adequate temperature control
- Adequate water supply
- Provision for adequate disposal of biological and non-biological waste
- Air Conditioning
- Clean and well maintained work surfaces *(*Refer to *IBTS/RCI/SOP/0047)*
- Limit on excess noise
- Ergonomic space to facilitate good work flow

The IBTS facility department maintains all electrical services, air handling services, process water services, pest control, general cleaning, waste handling, facility maintenance, facility security and fire alarm systems
These are described in facilities SOPs
IBTS/FAC/SOP/0302
IBTS/FAC/SOP/0306
IBTS/FAC/SOP/0318
IBTS/FAC/SOP/0328
IBTS/FAC/SOP/0329
IBTS/FAC/SOP/0343
IBTS/FAC/SOP/0348

The RCI Laboratory maintains effective separation between adjacent laboratory Service departments.
This separation prevents the following:

- Incompatible activities operating in the same location
- Cross-contamination
- Excess noise levels

Where testing procedures pose a bio-hazard risk the RCI laboratory has equipment in place to prevent cross-contamination and to allow for containment as per *IBTS/RCI/SOP/0029.*

The RCI laboratory operates in an environment with adequate space that is conducive to quiet and uninterrupted work.

The Laboratory room temperature is monitored by the Rees Centron Environmental monitoring System. This is a high security environmental monitoring system which records temperatures at defined intervals under normal conditions i.e. within predetermined limits and more frequently during alarm conditions i.e. outside the predetermined limits. When the system alarms, the Rees Centron notifies appropriate personnel through the telephone system. The alarm status can be obtained from the REES system which indicates whether a temperature monitoring probe is not in alarm, pending alarm or is actually in alarm. All events are recorded in the REES on-line event log. Refer to *IBTS/REES/SOP/0001*

Storage and Disposal of dangerous materials are those specified by relevant regulations. Refer to the following:

- IBTS Parent Safety statement
- The RCI Laboratory has a procedure in place for the disposal of samples. Refer to *IBTS/RCI/SOP/0050.*

5.3 Equipment, Reagents and Consumables

5.3.1 Equipment

5.3.1.1 General

The RCI Laboratory is furnished with all items of equipment required for the provision of services (including sample preparation, processing, and examination, storage and Haemovigilance / Traceability activities).
For the selection, purchasing and management of equipment refer to the following;

- *IBTS/ADM/SOP/0001*
- *IBTS/ADM/SOP/0003*
- *IBTS/QA/VMP/0006*
- *IBTS/VAL/SOP/0006*
- *IBTS/VAL/SOP/0009*

The validation department monitors equipment as per maintenance / calibration schedules and replace equipment as needed to ensure the quality of examination results.

5.3.1.2 Equipment Acceptance Testing

The Validation Department implements a Validation Master Plan *IBTS/QA/VMP/0001* which requires that all new equipment (instruments, analytical systems, storage equipment etc.) that have a direct or indirect impact on Blood / Blood Product / Blood Product Quality to be suitably validated before being put into use. This demonstrates that they operate as per the manufacturer's requirements and ensures that they are suitable for their intended use. Records of all validations are maintained by the Validation Department.

All equipment / systems/ processes which have a direct or indirect impact on the quality of the service that require validation are identified. An RCI Laboratory Validation spread sheet for all of the equipment is available.

Ref *IBTS/VAL/RA/0070 and IBTS/VAL/SOP/0012*

Each item of equipment is uniquely labelled with an asset number.

5.3.1.3 Equipment Instructions for Use

Equipment is used only by trained authorised RCI Laboratory personnel. Procedures are in place for each piece of equipment, which detail the operation, maintenance, cleaning and calibration of the equipment. Instructions in the event of a breakdown are also detailed in these procedures. These procedures are reviewed every two years to ensure that they are current and in line with current practices and manufacturers recommendations.
Individual equipment procedures or user manuals, details the safety precautions to be adhered to when using equipment.
The laboratory follows manufacturer's instructions for the safe handling, transport, storage and use of equipment to prevent contamination or deterioration.

5.3.1.4 Equipment Calibration and Metrological Traceability

The validation department implements a Calibration and Maintenance Master Plan as described in *IBTS/QA/VMP/0006* which ensures that all equipment, instruments and systems included in the programme are maintained, calibrated and re-qualified to the required regulatory or pertinent standard to ensure fitness for use and maintenance of the validated state.

The Service or Calibration frequency is documented in the Equipment Schedule as per *IBTS/QA/VMP/0006*, (Equipment Schedule) and (Execution / Frequency). The equipment schedule is maintained by the Validation Department in conjunction with the User Department. This is supplemented by validation Plans and requalification protocols.

Many of the calibrations and preventative maintenance activities are performed by external service suppliers. A Service Level Agreement is in place for all external service suppliers used by the RCI Laboratory. All calibration and preventative maintenance checklists used for the RCI Laboratory equipment are internally approved by the User Department.

The status of calibration is clearly identified on the equipment by suitable labels which identify:

- Date of calibration.
- Calibration performed by.
- Date of next calibration.

Details and results of such calibrations are recorded by the Validation department and stored in the applicable equipment file.
This process is not applicable for analysers that require daily routine calibration. Examples are Ortho Vision and Astoria Pacific Continuous Flow Analyser.

Calibration includes:

a) Taking into account conditions of use and the manufacturers' instructions;
b) Recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;
c) Verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;
d) Recording the calibration status and date of recalibration;
e) Safeguards to prevent adjustments or tampering that might invalidate examination results.

Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.
NOTE Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.
Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

- Use of certified reference materials;
- Examination or calibration by another procedure;
- Mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

5.3.1.5 Equipment Maintenance and Repair

The validation department implements a Calibration and Maintenance Master Plan as described in *IBTS/QA/VMP/0006* and *IBTS/VAL/SOP/0008* which ensures that all equipment, instruments and systems included in the programme are maintained, calibrated and re-qualified to the required regulatory or pertinent standard to ensure fitness for use and maintenance of the validated state.

The Service or Calibration frequency is documented in the Equipment Schedule as per *IBTS/QA/VMP/0006*, (Equipment Schedule) and (Execution / Frequency). The equipment schedule is maintained by the Validation Department in conjunction with RCI. This is supplemented by validation Plans and requalification protocols.

The laboratory follows the IBTS Validation procedure for preventive maintenance which, at a minimum, follows the manufacturer's instructions. *Refer to IBTS/VAL/SOP/0008.*
Equipment shall be maintained in a safe working condition and in working order. This shall include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used.

The IBTS facility department maintains all electrical services, air handling services, process water services, pest control, general cleaning, waste handling, facility maintenance, facility security and fire alarm systems
These are described in facilities SOPs
IBTS/FAC/SOP/0302
IBTS/FAC/SOP/0306
IBTS/FAC/SOP/0318
IBTS/FAC/SOP/0328
IBTS/FAC/SOP/0329
IBTS/FAC/SOP/0343
IBTS/FAC/SOP/0348

Whenever equipment is found to be defective, it shall be taken out of service and clearly labelled. The laboratory shall ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The laboratory shall examine the effect of any defects on previous examinations and institute immediate action or corrective action (see 4.10).

Many of the calibrations and preventative maintenance activities are performed by external service suppliers. A Service Level Agreement is in place for all external service suppliers used by the RCI Laboratory. All calibration and preventative maintenance checklists used for the RCI Laboratory equipment are internally approved by RCI.

The RCI Laboratory decontaminates equipment prior to service, repair or de-commissioning as per *IBTS/VAL/SOP/0009*

Where repair and maintenance require the equipment to be moved from its working location, then prior to its return to routine use the equipment must be recalibrated or revalidated (if appropriate).
Refer to IBTS/QA/SOP/0061 and IBTS/VAL/SOP/0008.

5.3.1.6 Equipment Adverse Incident Reporting
When equipment is found to be defective, it is taken out of service, clearly labeled with an ‘Equipment Not in Use’ label. Refer to *IBTS/VAL/SOP/0009* procedure for the decommissioning of IBTS GMP equipment.
The equipment is appropriately stored until it has been repaired and shown by calibration, verification or testing to operate correctly. The Equipment Log is signed by the Chief Medical Scientist/Designee and the equipment is released and re-commissioned. The record of which is filed in the individual Equipment Files as per *IBTS/QA/SOP/0061*.
Unexpected breakdown of equipment which has a Quality impact will be documented using the Incident reporting system as per *IBTS/QA/SOP/0068*, investigated and reported to the manufacturer and appropriate authorities.

5.3.1.7 Equipment Records

Records are maintained for each item of equipment that contributes to the performance of examinations. Each piece of equipment has an associated equipment file which includes (but not limited) to:

Record ID	Record Description	Record Location
a.	Identity of equipment	Asset Number label is located on each piece of equipment and by validation spreadsheet
b.	Manufacturer's name, equipment type, makes model and serial number.	Validation Spreadsheet
c.	Supplier / Manufacturer contact person and telephone number.	Validation Dept file.
d.	Date of receipt and putting into service.	Validation Dept file.
e.	Current location.	Validation Spreadsheet
f.	Conditions when received e.g. new, used or reconditioned.	Validation Dept file.
g.	Manufacturer's instructions/ manual	Equipment validation documentation file
h.	equipment records that confirm initial suitability for use	Validation of Equipment – Validation Dept files and equipment logs. Calibration of Equipment – Validation Dept files and equipment logs.
i.	maintenance carried out and schedule for preventative	Preventative Maintenance of Equipment – Equipment PM schedule Future calibration and maintenance plan in Validation Spreadsheet
j.	Equipment performance records that confirm the equipments ongoing acceptability for use Copies / reports / certs of calibrations Verifications including dates / times / results Adjustments Acceptance criteria and due date of next calibration / verification	Validation Spreadsheets
k.	Damage, malfunction, modification and repair	Unplanned maintenance records held by validation dept and equipment logs.

These records are readily available for review and will be maintained as per *IBTS/DP/POL/0002*. (Refer to 4.13)

5.3.2 Reagents and Consumables

5.3.2.1 General

The RCI Laboratory has a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables. Refer to *IBTS/RCI/SOP/0030* and *IBTS/ADM/SOP/0003.*

5.3.2.2 Reagents and Consumables – Reception and Storage

Reagents and consumables may be received either into the Stores Department, or directly into the RCI Laboratory itself. All purchased items are stored in a manner which prevents damage or deterioration. All received reagents and consumables are stored according to manufacturer's specifications and instructions
Refer to *IBTS/ADM/SOP/0002.*

5.3.2.3 Reagents and Consumables – Acceptance Testing

Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, are verified for performance before use in examinations.
Consumables that can affect the quality of examinations are verified for performance before use in examinations. This is performed through batch acceptance testing of each new lot or shipment.
Changes to reagents or formulations are managed as per IBTS change management procedure- *IBTS/QA/SOP/0006.*

Both the RCI laboratory and the materials management section of the QC department provide inspection and testing services for reagents and materials used by RCI. A list is maintained as per *IBTS/RCI/LIST/0001*. The full list of RCI materials is *IBTS/RCI/LIST/0002*

5.3.2.4 Reagents and Consumables – Inventory Management

The RCI Laboratory has an established inventory control system for reagents and consumables which separate uninspected and unacceptable reagents and consumables form those that have been accepted for use.
Refer to *IBTS/RCI/SOP/0030.*

5.3.2.5 Reagents and Consumables – Instructions for Use

Instructions for the use of reagents and consumables, including those provided by the manufacturers are readily available and managed by Materials Management.

5.3.2.6 Reagents and Consumables – Adverse Incident Reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables are investigated and reported to the manufacturer and appropriate authorities, as required. Investigation of incidents is per IBTS/QA/SOP/0068 and the QA department may determine corrective actions such as reporting of the incident to the manufacturer or appropriate authority. In addition the IBTS Biovigilance Officer may report to competent authorities as per requirements for Medical Device vigilance reporting

5.3.2.7 Reagents and Consumables – Records

Records are maintained for each reagent and consumable that contributes to the performance of examinations. These records include but are not limited to the following:

a) identity of the reagent or consumable,
b) manufacturer's name and batch code or lot number,
c) contact information for the supplier or the manufacturer,
d) date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service,
e) condition when received (e.g. acceptable or damaged),
f) manufacturer's instructions,
g) records that confirmed the reagent's or consumable's initial acceptance for use,
h) Performance records that confirm the reagents or consumables ongoing acceptance for use.

Both the RCI laboratory and the materials management section of the QC department provide inspection and testing services for reagents and materials used by RCI. A list is maintained as per *IBTS/RCI/LIST/0001*. The full list of RCI materials is *IBTS/RCI/LIST/0002*

5.4 Pre-Examination Processes

5.4.1 General

The RCI Laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations. The Request Forms, Request for Red Cell Immunohaematology Investigation (BT - 0345) and Blood Group Compatibility Request Form (BT - 0007), contain sufficient information to identify the patient and the authorised requester, as well as providing pertinent clinical data.

5.4.2 Information for Patients and Users

Specific instructions for the delivery of primary specimens are documented and implemented by RCI Laboratory management through *IBTS/RCI/CM/0001* which is made available to all the users of the RCI Laboratory Service through the website with the following address: https://www.giveblood.ie/Clinical-Services/Red-Cell-Immunohaematology-Diagnostics/

The following is available for users (customers) of the service

- *IBTS/QA/QM/0001*
- *IBTS/RCI/LM/0001*
- RCI customer manual, *IBTS/RCI/CM/0001*
- Address label
- BT – 0345- sample request forms

The RCI Customer Manual

The RCI customer manual, *IBTS/RCI/CM/0001*, which is located on the IBTS website provides information to users of the laboratory service and includes, as appropriate:

a) Location of the laboratory
b) Clinical Services offered by the Laboratory including examinations referred to other laboratories
c) Opening hours of the laboratory
d) the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values;
e) Instructions for completion of the request form;
f) Instruction for preparation of the patient;
g) Instructions for patient-collected samples;
h) Instructions for transportation of samples, including any special handling needs;
i) Any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);
j) The laboratory's criteria for accepting and rejecting samples;
k) A list of factors known to significantly affect the performance of the examination or the interpretation of the results;
l) Availability of clinical advice on ordering of examinations and on interpretation of examination results;
m) The laboratory's policy on protection of personal information;
n) The laboratory's complaint procedure.

5.4.3 Request form Information

The paper laboratory request form allows space for the inclusion of, but is not limited to, the following:

a) Patient identification, including gender, date of birth, and the location/contact details of the patient, and hospital number,
b) Name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details,
c) Type of primary sample and, where relevant, the anatomic site of origin,
d) Examinations requested,
e) Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes,
f) Date and, where relevant, time of primary sample collection,
g) Date and time of sample receipt.
The laboratory does not accept any samples without a request form.

Refer to section 4.4.1 for a list of the current request forms.
Refer to *IBTS/RCI/SOP/0003.*

5.4.4 Primary Sample Collection and Handling

5.4.4.1 General

RCI have documented procedures for the proper collection and handling of primary samples. These are available to all those responsible for primary sample collection, on SmartSolve and the IBTS website through the

RCI customer Manual, *IBTS/RCI/CM/0001*.

5.4.4.2 Instructions for Pre-Collection Activities

The RCI customer manual, *IBTS/RCI/CM/0001* provides instruction for pre-collection activities and includes the following:

a) Completion of request form,
b) Preparation of the patient (Provided for by requesting hospital, not covered by IBTS),
c) Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives,
d) Special timing of collection, where needed,
e) Clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).

5.4.4.3 Instructions for Collection Activities

Collection activities do not take place in the IBTS. The RCI customer manual *IBTS/RCI/CM/0001* provides instruction for collection activities and includes the following:

a) Determination of the identity of the patient from whom a primary sample is collected,
b) Verification that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.],
c) Instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;
d) In situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff;
e) Instructions for labeling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected,
f) Recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time,
g) Instructions for proper storage conditions before collected samples are delivered to IBTS,
h) Safe disposal of materials used in the collection.

5.4.5 Sample Transportation

Transportation of samples to the RCI laboratory is the responsibility of the service requestor. Sample Delivery, Packaging and Transport Requirements are outlined in *IBTS/RCI/CM/0001*. Specimen transportation systems to the RCI laboratory are in place to ensure the timely arrival of specimens to the correct destination at minimum risk to both laboratory and non-laboratory personnel. These ensure that the validity of the test results is not compromised.

5.4.6 Sample Reception

The RCI laboratory procedure for sample reception, *IBTS/RCI/SOP/0003,* ensures that the following conditions are met;

a) Samples are unequivocally traceable, by request and labeling, to an identified patient or site. Specimen portions or aliquots are labeled so that they are traceable to the original primary specimen.

b) Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.

c) Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.

d) All primary samples received into the laboratory are recorded including the date and time of receipt, and the identity of the receiving person.

e) Authorised personnel evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).

f) The Laboratory has documented procedures in place for the receipt; labelling, processing and reporting of urgent primary specimens.

5.4.7 Pre-Examination Handling, Preparation and Storage

After the results have been reported, primary specimens are stored for a specified time under conditions which ensure the stability of specimen properties to enable the repetition of examinations or for additional examinations to be performed. *Refer to IBTS/RCI/SOP/0050.*

5.5 Examination Processes

Refer to *IBTS/RCI/CM/0001* for the Master lists of tests performed in the laboratory

5.5.1 Selection, Verification and Validation of Examination Procedures

5.5.1.1 General

The RCI Laboratory uses examination procedures which meet the needs of its users. These procedures are in widespread use and have been published or referenced in authoritative textbooks and journals. Performance specifications for each procedure used are in place and relate to the intended use of that procedure.

The RCI Laboratory uses only verified procedures for confirming that the examination procedures are suitable for the intended use. In the event that methods do not directly replicate manufacturer's instruction, they are validated prior to implementation either by running them in parallel with existing verified/validated methods or by an independent validation.

The RCI Laboratory validates all testing procedures before being introduced into routine use as per the requirements of the Validation Master Plan *IBTS/QA/VMP/0001*. Approved Validation Plans are used to confirm that the testing procedures are suitable for their intended use. Testing is performed as

indicated in the Validation Plan. Results of all validation testing are recorded and assessed against the acceptance criteria specified in the Validation Plan. A Validation File is maintained for each test method or group of parameters that constitute the method/test examination.
Any change required to a procedure must be processed through the Change Control system, *IBTS/QA/SOP/0006* and additional validation testing performed as required.
All test procedures are reviewed by the Senior Medical Scientists every two years. These reviews are documented on the Electronic Quality Management System.

5.5.1.2 Verification of Examination Procedures

Validated examination procedures used without modification are subject to independent verification by the RCI laboratory before being introduced into routine use. Approved IBTS Validation Plans are used to confirm that the testing procedures are suitable for their intended use. Testing is performed as indicated in the Validation Plan to meet the acceptance criteria. Acceptance criteria information is obtained from the manufacturer/method developer for confirming the performance characteristics of the procedure.
Where like for like replacement of test reagents are undertaken, this is managed through change management as per *IBTS/QA/SOP/0006* and the requirement for verification is documented and approved.

5.5.1.3 Validation of Examination Procedures

The laboratory validates examination procedures derived from the following sources:

a) non-standard methods,
b) laboratory designed or developed methods,
c) standard methods used outside their intended scope,
d) Validated methods subsequently modified.

The validation will be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.

When changes are made to a validated examination procedure, the influences of such changes are documented and, when appropriate, a new validation carried out. Refer to *IBTS/QA/SOP/0006.*

5.5.1.4 Measurement Uncertainty of Measured Quantity Values

As test results reported by RCI are qualitative in nature the laboratory satisfies the need for uncertainty estimates by following the method as per manufacturer's instructions, meeting performance requirements (e.g. acceptable EQA performance) and reporting the results as per published guidelines.

5.5.2 Biological Reference Intervals or Clinical Decision Values

Biological reference intervals are not applicable to the results of examination procedures produced by the RCI laboratory.

Clinical decision values are determined and defined for examination procedures where relevant. This information is provided on laboratory reports to assist in interpretation of the results by users.
A review of clinical decision values shall also take place if examination or pre-examination procedures are changed. For example, this review is undertaken when a test method is changed by the testing laboratory.
Refer to *IBTS/RCI/CM/0001* and *IBTS/RCI/SOP/0002*.

5.5.3 Documentation of Examination Procedures

Examination procedures in the form of RCI Laboratory Standard Operating Procedures (SOPs) are in place and available on SmartSolve.
The exact details of the procedure are written in clear, concise instructions which follow a logical order, using uniform language and terms as described in *IBTS/QA/SOP/0071* with reference to *IBTS/QA/SOP/0143* for document revision.
Any other documents e.g., SOP attachment that summarise key information can only be issued through SmartSolve for use as a quick reference at the workbench and are traceable to the SOP governing their use.

The examination/test procedures for RCI Laboratory reagents are based in whole or in part on package inserts, and instructions from the manufacturer.

When examination procedures are changed so that results or their interpretation may be significantly different, the implications are explained to the customers, prior to the introduction of the change as per *IBTS/QA/SOP/0006*.

5.6 Ensuring Quality of Examination Results

5.6.1 General

The laboratory ensures the quality of examinations by performing them under defined conditions.
Appropriate pre and post-examination processes are implemented.
The laboratory does not fabricate any results.

5.6.2 Quality Control

5.6.2.1 General

The RCI Laboratory implements internal quality control systems that verify the attainment of the intended quality of results.

Both Internal and External (Inter-Laboratory NEQAS QA Scheme) quality control programmes are performed.
Internal Quality Assurance (QA) is carried out on a daily basis. All results are checked by Medical Scientists, logged and maintained in the RCI laboratory. QA results are regularly monitored by the Senior Medical Scientist, Chief Medical Scientist, Head of Testing and National QA Manager as a primary indicator of the Quality system in place in the laboratory.

External QA Scheme results are reviewed as per *IBTS/RCI/SOP/0061*.

No examination test result is accepted where internal QA controls fail. The examination will be repeated. The error will be investigated where necessary.

Trends and patterns are also investigated as part of Annual Quality Management Review meetings , and for the Annual Quality Report. Refer to *IBTS/RCI/SOP/0066.*

External QA Schemes are also an integral part of the Competency / proficiency testing process in the RCI Laboratory, where Medical Scientists working in the RCI Laboratory carry out at least one EQA procedure annually. Refer to *IBTS/RCI/SOP/0061* and *IBTS/RCI/SOP/0028.*

5.6.2.2 Quality Control Materials

The laboratory makes use of quality control materials that react to the examining system in a manner as close as possible to patient samples.

Quality control of materials is carried out with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

5.6.2.3 Quality Control Data

The RCI laboratory has a procedure to prevent the release of patient results in the event of quality control failure. This is described in each test method SOP.

When the quality control rules are violated and indicate that examination results contain clinically significant errors, the results are rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The RCI laboratory also evaluates the results from patient samples that were examined after the last successful quality control event.

Quality control failures are investigated and a non conformance recorded if relevant and appropriate. Repeated quality control failures are reviewed to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded. Refer to *IBTS/RCI/SOP/0066.*

5.6.3 Inter-laboratory Comparisons

5.6.3.1 Participation

The RCI Laboratory participates in inter-laboratory comparisons organized by external quality assessment schemes as per *IBTS/RCI/SOP/0061*. The RCI laboratory also participates in inter-laboratory comparisons as described in *IBTS/RCI/SOP/0017*.
Inter-laboratory comparison programmes are in substantial agreement with I.S. EN ISO/IEC 17043. External quality assessment programmes provide clinically relevant challenges that mimic patient specimens and have the effect of checking the entire examination process, including pre- and post-examination procedures.

5.6.3.2 Alternative Approaches

Where formal inter laboratory comparison programmes are not available, the RCI Laboratories may utilise externally derived challenge materials such as exchange of specimens with other laboratories to verify the test method. RCI Laboratory Management monitors the results of this method of inter laboratory comparison and participates in the implementation and recording of corrective actions as specified in 5.6.4.

5.6.3.3 Analysis of Inter-laboratory Comparison Samples

The RCI laboratory integrates the inter-laboratory comparison samples in a manner that follows, as much as possible, the handling of patient samples. This includes the examination by personnel who routinely examine patient samples.

The RCI laboratory does not communicate with other participants in the inter-laboratory comparison programme until after the date for submission of the data.

5.6.3.4 Evaluation of Laboratory Performance

RCI Management monitors the results of external quality assessments and any failures are documented, investigated and resolved as per the Quality Incident Reporting Procedure *IBTS/QA/SOP/0068*. The results of the assessments are discussed at the meeting with all relevant staff in conjunction with the Medical Department as per *IBTS/RCI/SOP/0066*. The Chief Medical Scientist in the RCI Laboratory in conjunction with the Senior Medical Scientists in the RCI laboratory prepares a review of these results for the Annual Report.
The results are reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded as per *IBTS/RCI/SOP/0066*.

5.6.4 Comparability of Examination Results

To ensure that examination results produced by different test methods or analysers produce comparable results EQA samples are tested using both manual and automated techniques and on all analysers. Significant deviations will be raised as non conformances. Where such deviations occur, any implications for clinical practice will be reviewed and users will be notified where relevant. Appropriate actions will be taken and reviewed for effectiveness.

5.7 Post-examination Processes

5.7.1 Review of Results

Only authorised, trained personnel shall review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorise the release of the results. The procedure to be applied to the review and release of results, including urgent results is defined in individual test procedures and *IBTS/RCI/SOP/0002*.

5.7.2 Storage, Retention and Disposal of Clinical Material

All clinical material i.e. primary specimens are retained and stored in accordance with *IBTS/RCI/SOP/0050*, thus ensuring the validity of repeat examinations.
IBTS/RCI/SOP/0050 includes the length of time clinical samples are to be retained by the nature of the sample, the examination and any applicable requirements.

Specimens are finally disposed of in accordance with *IBTS/RCI/SOP/0050* and in accordance with the RCI Laboratory Safety Manuals. Safe disposal of specimens no longer required for examination are carried out in accordance environmental health and safety requirements as per *EHS/1000-0705/2007/RevB.*

5.8 Reporting of Results

5.8.1 General

The RCI Laboratory has defined the format and the medium of the reports, refer *IBTS/QA/SS/0453*.
The RCI laboratory produces the results of examinations in eTraceline, which clearly, correctly and unambiguously presents the examination results and all other relevant information, which is comprehensive and clinically useful.
The electronic report is printed as a hardcopy for issue to requestors

Hardcopy reports are issued to the Referring hospitals Blood Transfusion Laboratory and are posted in envelopes marked 'Private & Confidential-laboratory report enclosed' to named Laboratory personnel/clinicians/designees (where indicated) or directly to the referring Laboratory. Compatibility results reports are held in the Hospital Services area for issue with the units as required. Where units are being issued on a specimen for compatibility testing or on a referred specimen a compatibility report will accompany the units. RCI Laboratory Senior Management Team shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval.

Copies of reported results are retained electronically on eTraceline. Back-Copies of reported results are also retained in hardcopy folders by the RCI Laboratory in a dedicated filing cabinet in the laboratory in alphabetical order such that prompt retrieval of the information is possible. All records and reports are retained as per *IBTS/DP/POL/0002*.

Result Reports are reviewed and signed by the Chief Medical Scientist (or designee), referred to the Consultant Haematologist/Laboratory Director for authorisation and signing and additional clinical comment if required. This is described in *IBTS/RCI/SOP/0002*.

The RCI laboratory shall notify the requestor when an examination is delayed that could compromise patient care.

5.8.2 Report Attributes

The RCI laboratory ensures that the report at meet the customer needs as per *IBTS/RCI/SOP/0002*:

a) Comments on sample quality that might compromise examination results,
b) Comments regarding sample suitability with respect to acceptance/rejection criteria
c) Critical results, where applicable,
d) Interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (Refer to 5.9.1) in the final report.

Risk levels for specific test results are also included [e.g. antenatal patients with clinically significant alloantibodies where there is a risk of Haemolytic Disease of the Fetus or Newborn (HDFN)]

Recommendations are also made, regarding repeat testing intervals, referral to Specialist Units, or referral to International Blood Group Reference Laboratories for further investigations.

5.8.3 Report Content

The report includes, but is not limited, to the following:

a) Clear, unambiguous identification of the tests performed.
b) Identification of the RCI Laboratory which issued the report.
c) Identification of all examinations that have been performed by a referral laboratory
d) Unique identification (History Number / MRN) and location of the patient and destination of the report (Hospital).
e) Name and contact details, of the requester
f) Date of primary sample collection, when available and relevant to patient care, and date and time of receipt by the RCI Laboratory.
g) Primary sample type (available on request).
h) Measurement procedure, where appropriate
i) Results of the examination reported in SI units or units traceable to SI units where applicable, (antibody Quantitation reported in International Units per mL {IU/mL})
j) Biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where relevant.
k) Interpretation of results, where required.
l) Other comments such as cautionary or explanatory notes (e.g. quality or adequacy of primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure).
m) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available

n) identification of the person(s) reviewing the results and authorising the release of the report
o) Date and time of release of report.
p) Page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.).

5.9 Release of Results

5.9.1 General

The RCI laboratory SOP *IBTS/RCI/SOP/0002* clearly describes the procedure for the release of examination results, including details of who may release results and to whom.

This procedure ensures that the following conditions are met:

a) The test report indicates if the quality of the primary sample received was unsuitable for examination or could have compromised the result e.g. lipaemia, haemolysis. Where a primary sample is deemed ‘unsuitable for analysis’ a new sample is requested.
b) The RCI Laboratory has procedures in place for immediate notification of a clinician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established “alert” or “critical” intervals. Refer to *IBTS/MED/POL/0009*.
A record of the contact with the clinician will be recorded on the original request form (*IBTS/RCI/SOP/0001 attachment 6.2 or 6.3*), (and may also be recorded on the associated worksheet) detailing the date and time of contact, the message relayed, the contact person and the Scientist who reported the event.
c) Results are legible, without mistakes in transcription, and reported to persons authorised to receive and use the information.
d) For results transmitted as an interim report the final report is always forwarded to the requester.
e) In *IBTS/RCI/SOP/0002* the RCI Laboratory has clearly documented procedures for the release of test results including details of who may release results and to whom. The procedures ensure release of results to requesting clinicians / requesting laboratories only. Results are not reported to patients.

5.9.2 Automated Selection and Reporting of Results

The RCI laboratory does not utilise automatic selection and reporting of results at this time.

5.9.3 Revised Reports

The RCI Laboratory has described the alteration/ amendment of reports in *IBTS/RCI/SOP/0002*.

a) The revised report is clearly identified as a revision and includes reference to the date and patient identity in the original report

b) The customer is made aware of the revision
c) The revised record shows the time and date of the change and the name of the person responsible for the change
d) Results that have been available for clinical decision making and revised shall be retained in subsequent cumulative reports and be clearly identified as having been revised, by the Laboratory Consultant making the alteration by a signature and date of the alteration on the report.

5.10 Information Management

5.10.1 General

The RCI Laboratory has access to the data and information needed to provide a service which meets the needs and requirements of the user.
The RCI laboratory refers to *IBTS/DP/POL/0001* to ensure the confidentiality of patient information.

The Laboratory information system in use in the RCI laboratory is eTraceline.

Ancillary systems within the RCI Laboratory include:

- eProgesa (Blood Establishment Computer System)
- Q-Pulse (EHS Reporting and doc control system)
- SmartSolve (Quality Management software)
- REES (Temperature Monitoring System)
- Microsoft Office Applications, e.g., Word and Excel
- eBOSS

5.10.2 Authorities and Responsibilities

The IBTS ensures that the authorities and responsibilities for the management of the information systems are defined, including the maintenance and modification to the information system(s) that may affect patient care, *IBTS/QA/QM/0001*.

The RCI laboratory defines the authorities and responsibilities of all personnel who use eTraceline as per *IBTS/QA/SS/0453* in particular those who:

a) Access patient data and information,
b) Enter patient data and examination results,
c) Change patient data or examination results,
d) Authorise the release of examination results and reports.

5.10.3 Information System Management - eTraceline

The LIS used for the collection, processing, recording, reporting, storage or retrieval of examination data and information, eTraceline, is:

a) Validated by the supplier and verified for functioning by the Department before introduction, with any changes to the system authorised, documented and verified before implementation;(Refer to *IBTS/QA/VMP/0001)*

b) Documented, and the documentation, including that for day to day functioning of the system, readily available to authorised users;
c) Protected from unauthorised access. Equipment, including hardware, software and analytical systems are safeguarded from adjustments or tampering that might invalidate examination results. This is accomplished through the use of locked facilities and the use of password. Refer to *IBTS/IT/POL/0015.*
d) Safeguarded against tampering or loss
e) Operated in an environment that complies with supplier specifications or, in the case of non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription *(*Refer to *IBTS/QA/VMP/0001)*
f) Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions. Refer to *IBTS/LABPT/UG/0001.*
g) In compliance with national or international requirements regarding data protection with reference to *IBTS/DP/POL/0001*.

The RCI Laboratory verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices).

When new examination or automated comments are implemented, the laboratory verifies that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory has documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service. Refer to *IBTS/RCI/SOP/0063.*

12 LABORATORY REQUIREMENTS NOT DESCRIBED IN ISO 15189

12.1. Transport

The storage, transport and distribution conditions of blood and blood components comply with the requirements of Statutory Instrument S.I. No. 360 of 2005 European Communities (Quality and Safety of Human Blood and Blood Components). Refer to *IBTS/QA/QM/0001*.

12.2. Blood Component Storage

Refer to Blood Establishment requirements in *IBTS/QA/QM/0001*.

12.3. Distribution

All distribution of blood components under the control of the RCI laboratory

is operated as per IBTS Blood Establishment distribution procedures, *IBTS/QA/QM/0001, IBTS/DSP/SOP/0050* and *IBTS/DSP/SOP/0060*.

13 TRACEABILITY REQUIREMENTS

13.1. Traceability

13.1.1. SI 547 European Community (Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations 2006 requires that the IRISH BLOOD TRANSFUSION SERVICE, where it acts as a hospital blood bank, has a system in place to trace the final fate of each and every unit of blood component supplied (i.e. 100% traceability). See *IBTS/QA/QM/0001* for description of blood establishment traceability

13.1.2. The IBTS maintains a system utilising a unique identification and labelling utilising both eProgesa and eTraceline. This is described in *IBTS/QA/QM/0001* for IBTS blood establishment (eProgesa) and *IBTS/RCI/SOP/0064* for the RCI laboratory (eTraceline)

13.1.3. The Irish Blood Transfusion Service in its agreement for the supply of blood and blood components and the provision of other services with its user hospitals has identified responsibilities for all parties in relation to traceability and storage. The Service Level Agreement (SLA) notes inter alia that "the hospital shall ensure the traceability of blood and blood components from the point of receipt of the blood or blood components by the hospital to its final use, or its return to the Irish Blood Transfusion Service for its disposal"; and that "where the IBTS acts as hospital blood bank, the hospital is required to notify IBTS of the final fate of each unit of blood and blood component supplied'.

13.1.4. It is the responsibility of these hospitals to have procedures in place when it issues units of blood or blood components for transfusion to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.

13.1.5. The RCI laboratory provides a routine Blood Bank service for a small number of Hospitals with no blood transfusion laboratory.

- Our Lady's Hospice, Harolds Cross,
- Blackrock Hospice
- Royal Victoria Eye & Ear Hospital.

13.1.6. The Chief Medical Scientist is responsible for establishing, maintaining and implementing a system to track donations issued by RCI to the above hospitals for which the IBTS provides a routine hospital blood bank service. This is described in *IBTS/RCI/SOP/0064*

13.1.7. The RCI laboratory utilises a 'Bag & Tag' traceability system. The Bag & Tag Label BT-396 is attached using a plastic tie onto all blood / blood components.

13.1.8. The label allows for the tracking and tracing of the blood / blood product from the RCI Laboratory to its final destination. It is the responsibility of the HBB receiving the blood / blood component to perform the appropriate checks prior to administration of the blood / blood components as per their SOPs.

13.1.9. The Traceability Labels (blue section of *BT - 0396*) are returned by the Hospital are inspected by the RCI laboratory staff (refer to *IBTS/RCI/SOP/00*64, to ensure that all of the relevant details have been completed as follows:

- Date of transfusion
- Time of transfusion
- Name and signature of the person confirming that the named patient received this blood component.
- Hospital
- Ward

13.1.10. Where the RCI acts as HBB and when blood components have been transfused, the date given, time given and the signature of the Nurse/Doctor who administered the transfusion is completed on the blue section of the bag and tag label. It is the responsibility of the hospital haemovigilance officer/ nominee to ensure the prompt return of fully completed section of the compatibility label to the RCI laboratory.

13.1.11. Where a blood component is issued by the RCI laboratory but is NOT transfused, this unit should be discarded by the hospital or returned to the IBTS. The traceability tag must be returned to the IBTS to ensure proper fating. Ref *IBTS/RCI/SOP/0064*. This SOP contains forms to aid in traceability in these circumstances including transfusion confirmation of non-assigned blood components. This is used where RCI laboratory acts as HBB and blood components that were labelled as emergency stock and issued to a facility, have been transfused to a patient.

13.1.12. A hard copy of traceability labels are retained by the IBTS for 30 years as per IBTS/DP/POL/0002 and as required under SI 547.

13.1.13. Where the RCI lab acts as a referral laboratory, it is the responsibility of the referring Hospital Blood Bank to manage traceability of the unit.

14 HAEMOVIGILANCE REQUIREMENTS

14.1. General

Haemovigilance is defined as ‘a set of surveillance procedures from the collection of blood / blood products to the follow up of recipients, to collect and access information on unexpected or undesirable effects resulting from the use of blood / blood products, and to prevent their re-occurrence’.
The information provided by Haemovigilance may contribute to improving the following:

- Provides the Medical profession with a reliable source of information about adverse events and reactions associated with blood collection and transfusion.
- Indicates corrective measures required to prevent a reoccurrence of incidents or dysfunctions in the transfusion process
- Warning system for hospitals and blood establishments about adverse events and reactions that could involve more individuals than a single recipient, including transfusion transmitted infections and defects related to packs, materials, solutions and blood processing.

14.1.1 The RCI laboratory provides a routine Blood Bank service for the following hospitals;

- Our Lady's Hospice, Harold's Cross
- Blackrock Hospice
- Royal Victoria Eye & Ear Hospital.

14.1.2 These hospitals are responsible for managing haemovigilance within the clinical area. The hospitals must employ a haemovigilance officer on site. The IBTS Consultant haematologist and other medical staff will provide guidance when / where required to hospital clinical staff on haemovigilance issues. The IBTS has SLA's in place with these hospitals which clearly defines the Hospital's responsibilities in this regard.

14.1.3 The Hospital must ensure that the Haemovigilance activities meet the requirements of article 14/15 of the IMB/INAB, Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC in compliance with ISO 15189: 2007. Refer to Haemovigilance handbook, *BT - 0423*.

14.2. Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs)

14.2.1 The IBTS conforms to Directive 2005/6/1/EC implementing Directive 2002/98/EC as regards notification of Serious Adverse Reactions (SARs) and Events (SAEs), transposed into Irish law by SI 547 of 2006.

14.2.2 It is the responsibility of the IBTS as a Blood Establishment to report all SAEs relating to collection, testing, processing, storage and distribution of blood and blood components by the Irish Blood Transfusion Service to the competent authority, the Health Products Regulatory Authority (HPRA). The IBTS also reports to the National Haemovigilance Office. Ref *IBTS/QA/QM/0001 and IBTS/QAV/SOP/0002*

14.2.3 It is the responsibility of the IBTS as a referral laboratory and when acting as a HBB to report all SAEs relating to those activities, to the competent authority, the Health Products Regulatory Authority (HPRA). The IBTS also reports to the National Haemovigilance Office. Ref *IBTS/QA/QM/0001 and IBTS/QAV/SOP/0002*

14.2.4 Where the IBTS acts as a referral laboratory for Hospital Blood Banks in its agreement (SLA) for the supply of blood and blood components and the provision of other services with its user hospitals has identified responsibilities for all parties in relation to the obligations to report Serious

Adverse Events (SAEs) and Serious Adverse Reactions (SARs). The Service Level Agreement between the Irish Blood Transfusion Service and the hospital notes "The hospital shall report in writing and without delay all Serious Adverse Events and Serious Adverse Reactions to the National Haemovigilance Office of the Irish Blood Transfusion Service. The hospital should take note of the requirements under the regulations for mandatory reporting of Serious Adverse Events and Serious Adverse Reactions".

14.2.5 Where the RCI laboratory acts as a Hospital Blood Bank it is the responsibility of the hospital to have a haemovigilance system in place for the review of all blood transfusion adverse events / reactions occurring within the hospital and to ensure that all SAEs and SARs are reported to the National Haemovigilance Office (NHO) as defined by the NHO and in conformance with their protocols. The Hospital Haemovigilance Officer must liaise with the IBTS Biovigilance Officer to prevent duplication of reporting.

14.2.6 It is the responsibility of the hospital, for which the IBTS act as their Hospital Blood Bank, to have in place haemovigilance procedures for the clinical investigation and management of adverse events and reactions occurring in relation to transfusion of blood and blood components.

14.2.7 In the event of an adverse transfusion reaction relating to a component, whether issued to a Hospital Blood Transfusion Laboratory or directly to a clinical transfusion facility where the IBTS acts as the hospital blood bank, the hospital must inform the RCI Laboratory immediately, by telephone, to ensure prompt recall of co-components where indicated.

14.2.8 Serological transfusion reaction investigations are undertaken as per *IBTS/RCI/SOP/0074.* Blood component suspected adverse reactions are progressed through the IBTS Complaints Procedure as outlined in *IBTS/QA/SOP/0063*.

14.2.9 The IBTS Consultant Haematologist / Specialist Medical Officer will provide immediate clinical advice on the investigation of such reactions and will liaise with the hospital clinical staff and Haemovigilance Officer in relation to the clinical events and investigation outcomes.

14.2.10 A report will be issued to the hospital clinician outlining the results of all the investigations performed.

14.2.11 If the criteria meet those for the reporting of a serious adverse reaction to the NHO the IBTS Consultant Haematologist will advise on the type of reaction and advise the hospital Haemovigilance Officer regarding reporting of the reaction to the NHO as per the NHO Handbook.

14.2.12 Where the RCI laboratory acts as a HBB, in the case of an SAE that has observed in the hospital, the hospital must inform the RCI Laboratory.

14.2.13 The IBTS Biovigilance Officer will assess all potential SAEs occurring in relation to the diagnostic services provided to hospitals by the RCI laboratory, both as a referral service or when acting as a HBB. These will be reported to the National Haemovigilance Office and/ or the HPRA if deemed necessary according to *IBTS/QAV/SOP/0002*

14.2.14 A review of serious adverse reactions and serious adverse events is performed at the RCI Quality Review Meetings and should also be undertaken at each Hospital Transfusion Committee Meeting. The review is performed at the RCI Quality Review Meetings as per IBTS/RCI/SOP/0066. The IBTS Consultant Haematologist will attend such meetings.

14.2.15 The hospitals where the IBTS acts as a HBB arranges a Hospital Transfusion Committee meeting biannually. The following representatives from the IBTS are in attendance: Consultant Haematologist, RCI Chief Medical Scientist & Biovigilance Officer. SAEs and SARs are discussed at this meeting.

14.2.16 It is the responsibility of the IBTS Biovigilance Officer to complete an ANSAE (Annual notification of serious adverse event) report on behalf of the IBTS Blood Establishment (may include SAEs relating to referral services) and also an ANSAE report where the IBTS acts as a hospital blood bank. While the hospital haemovigilance officer is responsible for reporting SARs occurring in the clinical setting, the IBTS Biovigilance Officer completes an ANSAR (Annual notification of a serious adverse reaction) report where the IBTS acts as a hospital blood bank.

14.2.17 The IBTS Biovigilance Officer submits the ANSAE and ANSAR reports to the National Haemovigilance Office (NHO) who submit this report to the competent authority, HPRA.

14.3. Medicinal Products

When an adverse reaction is reported from a hospital through a complaint ref. *IBTS/QA/SOP/0063* and is attributable to the quality or safety of a Medicinal Product, a Pharmacoviligance Form, located on the HPRA Pharmacovigilance website is completed by IBTS Biovigilance Officer. The adverse reaction is reported to the relevant manufacturer. Refer to *IBTS/QA/SOP/0063 and IBTS/MM/SOP/0009*.

15 ATTACHMENTS

15.1 Organisation Chart

RCI Organisation chart