Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Review

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Change Orders

Changes as described on Change Order: **Change Order No.**

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IBTS/CO/0057/25

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TITLE: IBTS RED CELL IMMUNOHAEMATOLOGY LABORATORY MANUAL

Change Description:

1. In Section 5 remove all detail that RCI is accredited by INAB and reference to list of accredited tests in the RCI customer manual
2. Under roles & responsibility of Chief Medical Scientist RCI remove text ' Oversee the RCI laboratory preparation for, and on-going compliance with, INAB (ISO15189) accreditation. Prepares and participates in ISO 15189 inspections and follows up on corrective actions for the RCI laboratory'
3. In section 5.5 rephrase conform to the requirements of ISO 15189, AML-BB and INAB requirements. To operate to ISO 15189 and AML-BB requirements '
4. in section 7 remove relevant to ISO 15189 accreditation from this sentence: See section 8 (ISO15189 Clause 5.2.2 & 5.4.1) for detailed responsibilities of the key roles relevant to ISO 15189 accreditation.
5. In section 9 remove the sentence: This is outside of scope of ISO 15189 accreditation for the RCI laboratory.
6. In section 4 Regulatory Requirements remove INAB
7. Load Version 7 of IBTS/RCI/LM/0001 on the website to allow users to cross reference with the customer manual
8. In section 11.1.3 update ISO 15189:2012 to ISO 15189:2022
9. Remove ref to IBTS/QA/SOP/0071 & 0156
10. Remove ref to IBTS/RCI/SOP/0017 & 0085
11. Remove references to ISO 15189 where it may be interpreted that RCI are accredited.

Reason for Change:

1. As per CC 050/25
2. As per CC 050/25
3. As per CC 050/25
4. As per CC 050/25
5. As per CC 050/25
6. As per CC 050/25
7. Customer manual refer out to the laboratory manual
8. Reflect change in standard CC 308/24
9. Ref CC 355/24 & IBTS/QA/POL/0002
10. See IBTS/RCI/SOP/0061
11. As per CC 050/25

Change Order No.:

IBTS/CO/0057/25

Referenced Documents

BT - 0007	IBTS/LABPT/UG/0001	IBTS/RCI/SOP/0001
BT - 0345	IBTS/LABT/UG/0001	IBTS/RCI/SOP/0002
BT - 0566	IBTS/LABT/CS/0001	IBTS/RCI/SOP/0013
IBTS/ADM/POL/0001	IBTS/MED/SOP/0063	IBTS/RCI/SOP/0019
IBTS/ADM/SOP/0001	IBTS/MM/SOP/0004	IBTS/RCI/SOP/0028
IBTS/ADM/SOP/0002	IBTS/MM/SOP/0006	IBTS/RCI/SOP/0029
BT - 0396	IBTS/MM/SOP/0009	IBTS/RCI/SOP/0030
IBTS/ADM/SOP/0003	IBTS/MM/SOP/0010	IBTS/RCI/SOP/0047
IBTS/DP/POL/0001	IBTS/MM/SOP/0015	IBTS/RCI/SOP/0049
IBTS/DP/POL/0002	IBTS/MM/SOP/0016	IBTS/RCI/SOP/0050
IBTS/DP/POL/0008	IBTS/MM/SOP/0019	IBTS/RCI/SOP/0054
IBTS/DP/POL/0012	IBTS/MM/SOP/0036	IBTS/RCI/SOP/0061
IBTS/DP/POL/0018	IBTS/QA/AUTH/0001	IBTS/RCI/SOP/0063
IBTS/DP/SOP/0006	IBTS/QA/POL/0002	IBTS/RCI/SOP/0064
IBTS/DSP/SOP/0050	IBTS/QA/POL/0003	IBTS/RCI/SOP/0065
IBTS/DSP/SOP/0051	IBTS/QA/POL/0006	IBTS/RCI/SOP/0066
IBTS/DSP/SOP/0060	IBTS/QA/POL/0007	IBTS/RCI/SOP/0070
IBTS/EXT/DOC/0012	IBTS/QA/QM/0001	IBTS/RCI/SOP/0074
IBTS/EXT/DOC/0017	IBTS/QA/SOP/0006	IBTS/RCI/SOP/0076
IBTS/EXT/DOC/0033-39, 41-60, 63	IBTS/QA/SOP/0061	IBTS/RCI/SOP/0078
IBTS/FAC/SOP/0302	IBTS/QA/SOP/0062	IBTS/RCI/SOP/0080
IBTS/FAC/SOP/0306	IBTS/QA/SOP/0063	IBTS/RCI/SOP/0081
IBTS/FAC/SOP/0318	IBTS/QA/SOP/0068	IBTS/RCI/SOP/0084
IBTS/FAC/SOP/0324	IBTS/QA/SOP/0076	IBTS/RCI/SOP/0086
IBTS/FAC/SOP/0328	IBTS/QA/SOP/0088	IBTS/RCI/SOP/0088
IBTS/REES/SOP/0001	IBTS/QA/SOP/0143	IBTS/RCI/SOP/0089
IBTS/HR/JD/0001	IBTS/QA/SOP/0148	IBTS/RCI/SOP/0077
IBTS/HR/JD/0002	IBTS/QA/SOP/0161	IBTS/RCI/SOP/0046
IBTS/HR/JD/0003	IBTS/QA/SS/0453	IBTS/RR/BCP/0003
IBTS/HR/JD/0004	IBTS/QA/VMP/0001	IBTS/RR/BCP/0006
IBTS/HR/JD/0005	IBTS/QA/VMP/0006	IBTS/RR/POL/0002
IBTS/HR/JD/0011	IBTS/QA/UG/0001	IBTS/RR/POL/0003
IBTS/HR/JD/0012	IBTS/QAV/SOP/0002	IBTS/RR/SOP/0004
IBTS/HR/JD/0013	IBTS/RCI/CM/0001	IBTS/VAL/SOP/0001
IBTS/HR/JD/0014	IBTS/RCI/LIST/0002	IBTS/VAL/SOP/0005
IBTS/HR/JD/0015	IBTS/RCI/LIST/0005	IBTS/VAL/SOP/0006
IBTS/HR/JD/0016	IBTS/RCI/LIST/0006	IBTS/VAL/SOP/0008
IBTS/HR/JD/0017	IBTS/RCI/POL/0003	IBTS/VAL/SOP/0009
IBTS/IT/POL/0015	IBTS/RCI/POL/0004	RCI H&S Manual ID 62
IBT/IT/POL/0018	IBTS/RCI/RL/0001_1	HR Policy 5.1
IBTS/IT/SOP/0069	IBTS/RCI/RL/0001_2	HR Policy 12.2
IBTS/IT/QM/0001		

SmartSolve Roles

ISO SQS NBC	QA THOD IBTS	RCI SMS NBC
LM HT IBTS	QC MGR IBTS	RCI THOD NBC
MED CON IH NBC	QC RAM IBTS	RCI TMS NBC
QA BVO IBTS	RCI LA NBC	TDOQ
QA SPVR MRTC	RCI MS NBC	VAL MGR IBTS

Training Type

All Staff
Procedural

SmartSolve Document Category

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

TITLE: IBTS RED CELL IMMUNOHAEMATOLOGY LABORATORY MANUAL

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.* See also laboratory process flow for guidance (Att. 12.3 of this document).

The RCI Laboratory provides Red Cell Immunohaematology and Antenatal services for hospitals nationwide. The NBC RCI laboratory also provides an on-call reference service for emergency complex investigations. The services provided by the RCI Laboratory include:

- ABO/Rh typing, including blood group anomaly investigation
- Provision of crossmatched blood for patients with complex antibodies.
- Investigation of red cell antibodies including serologically complex cases.
- Investigation of Haemolytic Transfusion Reactions.
- Investigation of patients with positive direct antiglobulin tests.
- Investigation of Autoimmune Haemolytic Anaemia.
- Investigation of monoclonal antibody interference
- Investigation of Haemolytic Disease of the Foetus and Newborn (HDFN).
- Identification of pregnancies at risk of HDFN by Antenatal Screening (antibody quantitation and / or antibody titration 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, patients' pre-commencement of monoclonal therapy, and for patients with complex red cell antibodies.
- Phenotyping of donor red cells and provision of phenotyped blood when not in stock
- ABO/RhD and antibody investigation of donor samples on request (Blood Establishment authorisation)
- Clinical and scientific advice to hospital colleagues.
- Importation of blood for named patients

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.

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 SCOPE

The RCI Laboratory Manual aims:

- 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.

This document 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.

Section 8 of this manual is arranged so that each subsection is aligned with the numbering scheme of ISO 15189 (2022) standard.

4 REGULATORY REQUIREMENTS

Regulatory Document	IBTS document reference
S.I. No. 22 of 2000 The Blood Transfusion Service Board (Establishment) Order, 1965 (Amendment) Order, 2000.	*IBTS/EXT/DOC/0012*
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".	
S.I. No. 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.	
S.I. No. 547/06 - Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC".	
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".	
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.	*IBTS/EXT/DOC/0017*
ISO 15189:2022 - International Standard ~ Medical Laboratories – Particular requirement for Quality and Competence.	*IBTS/EXT/DOC/0033*

5 AUTHORISATION

The IBTS is authorised for testing as part of the Blood Establishment authorisation no. BE-002 issued by the HPRA. Refer to *IBTS/QA/AUTH/0001.* The laboratory complies with S.I. No.1 547 of 2006 incorporating Articles 14 and 15 of Directive 98/ 2002/EC (Traceability Requirements, Notification of SAR/E) for hospital blood bank (HBB) activities.

6 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 12.1.

7 RESPONSIBILITY

The following table contains roles and responsibilities for the below listed staff.

IBTS Role (job description reference in brackets)	Role description/ responsibilities	Deputy
Senior Medical Scientists *(IBTS/HR/JD/0013)*	Supervises day to day work-load in RCI Laboratory. Also participates in routine/complex testing in the RCI Laboratory. Provides advice to Medical Scientists. Reports to Chief Medical Scientist.	Senior / Medical Scientist
Medical Scientists *(IBTS/HR/JD/0014)*	Reports to Chief Medical Scientist. Performs day to day work-load in RCI Laboratory. Routine/complex testing in the RCI Laboratory / adhere to quality system in place. 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, including interpretation of results. 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

	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	
Medical Laboratory Assistant *(IBTS/HR/JD/0015)*	Provides laboratory assistance in the RCI Laboratory. Sample registration, Document retrieval, filing and charging. Samples 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

8 COMPLIANCE

4.0 GENERAL REQUIREMENTS

4.1 Impartiality

a) Laboratory activities are undertaken impartially. The laboratory is structured and managed to safeguard impartiality. To ensure this is achieved the laboratory ensures adherence to procedures and deviations are investigated.

b) Laboratory management is committed to impartiality.

c) The laboratory is responsible for the impartiality of its laboratory activities and does not allow commercial, financial or other pressures to compromise impartiality.

d) The laboratory monitors its activities and its relationships to identify threats to its impartiality. This monitoring includes relationships of its personnel.

e) If a threat to impartiality is identified, the effect is eliminated or minimised so that the impartiality is not compromised. The laboratory is able to demonstrate how it mitigates such threat.

Ref: *IBTS Policies and Procedures/Section 12/12.2*
Ref: *IBTS/LABT/CS/0001*
Ref*: IBTS/RCI/SOP/0080*
Ref: *IBTS/QA/SOP/0068*

4.2 Confidentiality

4.2.1 Management of Information

The laboratory is responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities. Management of patient information includes privacy and confidentiality. The laboratory informs the user and/or the patient in advance, of the information it intends to place in the public domain. Except for information that the user and/or patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and remains confidential.

Ref: *IBTS/DP/POL/0008*
Ref: *IBTS/DP/POL/0012*
Ref: *IBTS/DP/POL/0018;*

Ref: *IBTS/RCI/SOP/0050;*
Ref: *IBTS Policies and Procedures/Section 12/12.2*

4.2.2 Release of Information

When the laboratory is required by law or authorised by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released, unless prohibited by law.

Information about the patient from a source other than the patient (e.g. complainant. Regulator) is kept confidential by the laboratory. The identify of the source is kept confidential by the laboratory and is not shared with the patient unless agreed by the source.

Ref: *IBTS/DP/POL/0008*
Ref: *IBTS Policies and Procedures/Section 12/12.2*

4.2.3 Personnel Responsibility

Personnel, including any committee members, contractors, personnel of external bodies, and any other individuals with access to laboratory information acting on the laboratory's behalf are required to keep confidential all information obtained or created during the performance of laboratory activities.

Ref: *IBTS/LABT/CS/0001*
Ref: *IBTS Policies and Procedures/Section 12/12.2*

4.3 Requirements regarding patients

Laboratory management ensures that patients' well-being, safety and rights are the primary considerations. The laboratory has established and implemented the following processes;

a) opportunities for patient and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results. Refer to section 8.6.2.

b) provision of patients and users with publicly available information, including costs when applicable, and when to expect results about the examination process and when to expect results;

c) periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary. Refer to section 8.9.

d) where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;

e) treatment of patients, or samples with due care and respect;

f) obtaining informed consent when required. The is the responsibility of the service requestor. Refer to Section 7.2.4.3;

g) ensuring the on-going availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory;

h) making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;

i) upholding the rights of patients to care that is free from discrimination.

Ref: *IBTS/RCI/SOP/0066*
Ref: *IBTS/QA/SOP/0063*
Ref: *IBTS/RCI/CM/0001*
Ref: IBTS/QA/POL/0003
Ref: IBTS/QA/SOP/0068
Ref: Directive 2002/98/EC 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 [*IBTS/EXT/DOC/0012]*

5 STRUCTURAL AND GOVERNANCE REQUIREMENTS

5.1 Legal Entity

The laboratory or the organisation of which the laboratory is a part shall be an entity that can be held legally responsible for its activities. 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.

Ref: *IBTS/QA/QM/0001*

5.2 Laboratory Director

5.2.1 Laboratory Director competence

The laboratory is directed by a person, or persons, however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document. The duties and responsibilities of the laboratory director are documented.

Director of the RCI Laboratory is a Consultant Haematologist.
The responsibilities of the Laboratory Director include professional, scientific, consultative, or advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory. The duties and responsibilities of the Laboratory Director are outlined in Section 5.2.2.

5.2.2 Laboratory Director responsibilities

The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operation, so that risks to patient care and opportunities to improve are systematically identified, addressed & evaluated.

The following table indicates the roles and responsibilities, along with deputy for the Laboratory Director.

IBTS Role and/or delegated role *(job description ref. in brackets)*	Role description/ responsibilities within the QMS	Deputy
Consultant Haematologist RCI *(IBTS/HR/JD/0011)*	**The Consultant Haematologist for RCI is the designated Laboratory Director. The role and responsibilities are delegated and performed jointly with the IBTS roles described in this table under the detailed descriptions.**	**See below**
Consultant Haematologist RCI *(IBTS/HR/JD/0011)*	Provision of consultancy and clinical direction and leadership to the RCI Laboratory within the IBTS. Authorisation of patient reports.	Consultant Haematologists/ Specialised Medical Officers.
Chief Medical Scientist RCI (CMS RCI) *(IBTS/HR/JD/0012)*	Operation and administration of the RCI Laboratory and responsible for overseeing the management of the budgets, ensuring optimal utilisation of all resources to meet financial targets, and identifying any areas of concern to Medical Consultant and Head of Testing and finance department in a timely manner	Senior Medical Scientists RCI
Consultant Haematologist RCI Chief Medical Scientist RCI	The Consultant Haematologist RCI and the CMS RCI are jointly responsible for relating and functioning effectively with administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required	Consultant Haematologists/ Specialised Medical Officers. Senior Medical Scientists RCI
Quality Compliance and Regulatory Manager (QCRAM) *(IBTS/HR/JD/0003)*	Responsibility for interacting and communicating with the accrediting and regulatory agencies that the IBTS works with. (See quality manager section below)	Director of Quality & Compliance
Head of Testing *(IBTS/HR/JD/0005)* Chief Medical Scientist RCI	The Head of Testing and CMS RCI and are responsible for ensuring that the laboratory has an appropriate number of trained and competent staff with adequate supervision to meet the demands of the laboratory, regulations, and regulatory standards.	CMS RCI Senior Medical Scientists RCI

Head of Testing Chief Medical Scientist RCI	The Head of Testing has responsibility to assure that the RCI laboratory is operating in an efficient manner in compliance with their regulatory requirements and the standard set internally and to ensure commitment to Quality Standards is maintained as a priority consideration. The RCI CMS is responsible for the quality of all services of the laboratory, ensuring that the Quality Management System within the RCI department is maintained and constantly developed and addresses all aspects of the laboratory service including organisation, personnel, equipment, purchasing and inventory, process control, documents and records, information management, error and incident management, assessments, process improvement, facilities and safety.	CMS RCI Senior Medical Scientists RCI
Head of Testing IBTS Chief Medical Scientist RCI	The Head of Testing and CMS RCI are responsible for the implementation of a safe laboratory environment in compliance with good practice and applicable regulations and ensure that the facilities are appropriate for the services provided by the laboratory and ensure that personnel follow IBTS Health and Safety standards.	CMS RCI Senior Medical Scientists RCI
Consultant Haematologist RCI	The Consultant Haematologist RCI serves as a contributing member of the medical staff for the IBTS.	Consultant Haematologists/ Specialised Medical Officers
Consultant Haematologist RCI	Provision of clinical advice to hospital colleagues in haematology and foetal medicine with respect to the choice of examinations, use of the service and interpretation of examination results	Consultant Haematologists/ Specialised Medical Officers.
Consultant Haematologist RCI Chief Medical Scientist RCI	Responsible for all aspects of Risk management including, identification, review, mitigation & evaluation.	CMS RCI Senior Medical Scientists RCI
Head of Testing IBTS Chief Medical Scientist RCI	The Head of Testing and CMS RCI are responsible for all aspects related to purchasing and inventory management for RCI including the selection and monitoring	CMS RCI Senior Medical Scientists RCI

	of laboratory suppliers and identifying any areas of concern to the Laboratory Director and the finance department in a timely manner.	
Consultant Haematologist RCI Head of Testing IBTS Chief Medical Scientist RCI	The Consultant Haematologist RCI, Head of Testing and the CMS RCI are jointly responsible for selected referral laboratories and monitoring the quality of their service	Consultant Haematologists/ Specialised Medical Officers. CMS RCI Senior Medical Scientists RCI
Head of Testing IBTS Chief Medical Scientist RCI	The Head of Testing and CMS RCI are responsible for the development of training programmes for staff. The CMS RCI is responsible for the professional development of RCI staff, through promoting self-learning, formal courses, or formal and/or informal on the job training within the laboratory procedures. The CMS RCI with oversight from the Head of Testing is responsible to ensure all RCI staff participate and engage in the IBTS Personal Development programme.	CMS RCI Senior Medical Scientists RCI
Consultant Haematologist RCI, Head of Testing IBTS Chief Medical Scientist RCI	The Consultant Haematologist, Head of Testing and CMS RCI are jointly responsible for identifying and agreeing of metrics and relevant key performance indicators (KPIs) for the RCI laboratory. The Consultant Haematologist, Head of Testing and CMS RCI are jointly responsible for monitoring performance against these metrics & KPIs and implementing quality improvements.	Consultant Haematologists/ Specialised Medical Officers. CMS RCI Senior Medical Scientists RCI
Consultant Haematologist RCI	Provision of consultancy and clinical direction and leadership to the RCI Laboratory within the IBTS. Monitoring and authorisation of patient reports	Consultant Haematologists/ Specialised Medical Officers.
Consultant Haematologist RCI,	The Consultant Haematologist, Head of Testing and CMS RCI are jointly responsible for addressing any complaint, request or suggestion from staff and/or users of laboratory services	Consultant Haematologists/ Specialised Medical Officers.

Head of Testing IBTS Chief Medical Scientist RCI		CMS RCI Senior Medical Scientists RCI
Head of Testing IBTS Chief Medical Scientist RCI	CMS RCI and the Head of Testing ensure appropriate contingency plans are agreed and tested for all critical processes within RCI.	CMS RCI Senior Medical Scientists RCI
Consultant Haematologist RCI Chief Medical Scientist RCI	Planning and direction of research in RCI is completed in conjunction with the IBTS research department. Clinical governance and direction is provided by the Consultant Haematologist RCI and planning, execution and direction by the CMS RCI	Consultant Haematologists/ Specialised Medical Officers. Senior Medical Scientists RCI

5.2.3 Delegation of duties

The Laboratory Director may delegate either selected duties or responsibilities, or both to qualified and competent personnel and such delegation is documented. However, the laboratory director maintains the ultimate responsibilities for the overall operation of the laboratory. Delegation of duties is as described in the table in Section 5.2.2, and in *IBTS/RCI/LIST/0005*

The Laboratory Director maintains the ultimate responsibility for the overall operation of the laboratory.

5.3 Laboratory activities

5.3.1 General

The laboratory specifies and documents the range of laboratory activities, including laboratory activities performed at sites other than the main location (e.g. sample collection).

Ref: *IBTS/RCI/CM/0001*

5.3.2 Conformance with requirements

Laboratory activities are carried out in such a way as to meet the requirements of the users, regulatory authorities and organisations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.

5.3.3 Advisory activities

The laboratory ensures that appropriate laboratory advice and interpretation are available and meet the needs of patients and users.

The laboratory has established arrangements for communicating with laboratory users on the following when applicable:

a) advising on choice and use of examinations, including the type of sample, clinical indications and limitations of examination methods, and the frequency of requesting the examination;

b) providing professional judgements on the interpretation of the results of examinations;

c) promoting the effective utilisation of laboratory examinations;

d) advising on scientific and logistical matters such as instances of failure of sample(s)to meet acceptability criteria.

Ref: *IBTS/RCI/CM/0001*
Ref: *IBTS/MED/SOP/0063*
Ref: *IBTS/RCI/SOP/0066*
Ref: *IBTS/RCI/SOP/0002*
Ref: *IBTS/RCI/SOP/0003*

5.4 Structure and authority

5.4.1 General

The laboratory:

a) defines its organisation and management structure, its place in the parent organisation, and the relationships between management, technical operations and support services (See Attachment 12.2).

b) specify the responsibility, authority, lines of communication, and interrelationship of all personnel who manage, perform, or verify work affecting the results of laboratory activities (See Attachment 12.1).

c) specify the procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

The RCI Laboratory management team consists of the following:

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

In addition to the role and responsibilities previously outlined for the Laboratory Director (See Section 5.2.2), the following table indicates the general roles, responsibilities and reporting structure within the laboratory. Deputies for all key functions have also been outlined.

Ref: *IBTS/QA/QM/0001*
Ref: *IBTS/RCI/LIST/0005*
Ref: *IBTS/RCI/POL/0004.*

IBTS Role and/or delegated role *(job description ref. in brackets)*	Role description/ responsibilities within the QMS	Deputy
National Quality Assurance Manager (NQAM) IBTS ***(IBTS/HR/JD/0002)***	Responsible for senior level management of all Quality related activities through the effective implementation and administration of the IBTS Quality Management System under the requirements set out in IBTS/QA/QM/0001 Responsible for ensuring compliance with all relevant legislative requirements, outlined in IBTS Quality Manual, are met.	Quality Business Partner/QA Scientist
	Responsible for the regular review and reporting to IBTS management of trends and outputs of the IBTS Quality Management System and to continually drive improvements across all areas of the organisation. Responsible for providing management KPI/trend reports on the functioning and effectiveness of the Quality Management System within the IBTS. Responsible for meeting regularly with key stakeholders across all functions of the IBTS to review and improve the quality of products and services	
	Provides management of customer related issues through the effective administration of the Quality Customer Complaints System.	
Chief Medical Scientist RCI ***(IBTS/HR/JD/0012)***	Reporting to the Laboratory Director and the Head of Testing.	Senior Medical Scientists RCI

IBTS Role and/or delegated role *(job description ref. in brackets)*	Role description/ responsibilities within the QMS	Deputy
	Responsible for the overall operation and administration of the Red Cell Immunohaematology (RCI) Laboratory Responsible for the quality of all services of the RCI laboratory, ensuring that the RCI department operates within the IBTS Quality Management System Responsible for the quality of all services of the laboratory, ensuring that the Quality Management System within the RCI department is maintained and constantly developed and addresses all aspects of the RCI laboratory service.	ISO Quality Officer (Senior Medical Scientist)
	Reporting to laboratory management on the functioning and effectiveness of the quality management system. Responsible for initiating, supporting and implementing quality improvement initiatives in the RCI laboratory in consultation with laboratory management. Responsible for introducing and managing strategic developments agreed with IBTS and laboratory management within the RCI department and ensuring that the necessary resources are in place to meet departmental needs	
	Responsible for liaising with the RCI customers, determining their needs and requirements and	

IBTS Role and/or delegated role *(job description ref. in brackets)*	Role description/ responsibilities within the QMS	Deputy
	implementing any changes required to meet customer needs. The RCI CMS is responsible for communicating the needs and requirements of the customer to the RCI team	
Validation Manager **(Quality Department)**	The responsibility of the Validation Manager is to implement the Quality Management System across the organisation with respect to Management of Validation , Equipment Maintenance & Calibration	Validation Specialist
IT Quality Manager **(Quality Department)**	The responsibility of the IT Quality Manager is to implement the Quality Management System across the organisation with respect to the IT department and computer systems.	IT Quality Specialist/Validation Manager
Quality Compliance and Regulatory affairs Manager **(Quality Department)**	The responsibility of the Quality Compliance and Regulatory affairs Manager is to ensure the Quality Management System meets international best practice, GMP & regulatory requirements across the organisation. This includes management of Internal and external inspections to drive continuous improvement.	Director of Quality and Compliance/RP
Quality Control Manager **(Quality Department)**	The responsibility of the QC Manager is to implement the Quality Management System across the organisation with respect to Quality Monitoring, Environmental Monitoring AND Materials Management.	Senior Quality Scientist

IBTS Role and/or delegated role *(job description ref. in brackets)*	Role description/ responsibilities within the QMS	Deputy
Senior Quality Assurance Scientist/ Quality Business Partner (QBP) **(Quality Department)**	The Senior Quality Assurance Scientist/ Quality Business Partner (QBP) is responsible for the day to day administration of the QMS, in accordance with regulatory requirements. Reviews QA related records and partners with IBTS departments to ensure quality practices are compliant and to promote continuous improvement.	Quality Assurance Scientist

5.4.2 Quality management

The laboratory has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimise such deviations;

d) reporting to laboratory management of the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities.

Ref: *IBTS/RCI/SOP/0066*
Ref: *IBTS/QA/SOP/0068*

5.5 Objectives and policies

a) Laboratory management establishes and maintains objectives and policies (See section 8.2) for the laboratory to:

1) meet the needs and requirements of its patients and users;

2) commit to good professional practice;

3) provide examinations that fulfil their intended use;

4) operate to the requirements of AML-BB.

b) Objectives are measurable and consistent with laboratory policies. Laboratory management ensures that the objectives and policies are implemented at all levels of the laboratory organisation.

c) Laboratory management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

d) The laboratory establishes quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives.

Ref: *IBTS/RCI/SOP/0066*
Ref: *IBTS/RCI/SOP/0076*
Ref: *IBTS/QA/SOP/0006*

5.6 Risk management

a) Laboratory management establishes, implements, and maintains processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities. It develops actions to address both risks and opportunities for improvement (See section 8.5).

b) The laboratory director ensures that these processes are evaluated for effectiveness and modified when identified as being ineffective.

Ref: *IBTS/RCI/SOP/0080*
Ref: *IBTS/QA/QM/0001*
Ref: *IBTS/RR/POL/0002*

6 Resource requirements

6.1. General

Laboratory management ensures the laboratory has the available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.

6.2 Personnel

6.2.1 General

Laboratory management ensures:

a) Access to a sufficient number of competent persons to perform its activities.

b) All laboratory personnel, either internal or external, that could influence the laboratory activities act impartially & ethically, are competent and work in accordance with the laboratory's management system. All laboratory personnel, either internal or external work in accordance with the IBTS Quality Management System

c) The laboratory communicate to personnel the importance of meeting the needs and the requirements of users. 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. The effectiveness of the RCI laboratory is communicated during management review meetings, organisational meetings, circulation of management review meeting minutes, customer satisfaction surveys, and internal audit results.

d) All new employees attend a programme to introduce personnel to the organisation, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services. On-boarding and induction within the IBTS is described in the IBTS Human Resources Manual.

Ref: *IBTS/QA/QM/0001:*
Ref: *IBTS/LABT/CS/0001*
Ref: *IBTS/RCI/SOP/0028:*
Ref: *IBTS/RR/BCP/0006*
Ref: *IBTS/RCI/SOP/0066*
Ref: IBTS Policies and Procedures/Section 5/5.1

Ref: *IBTS Induction Checklist*

6.2.2 Competence requirements

a) The laboratory specifies the competence requirements for each laboratory function influencing results of its activities. This includes the requirements for education, qualification, training, re-training, technical knowledge, skills and experience.

Ref: Individual job descriptions IBTS/HR/JD/0001 -> 0005; IBTS/HR/JD/0011 -> 0017.

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.
c) Qualifications
d) Other Records Relating to Personal Health, including pre-employment

b) The laboratory ensures all personnel have the competence to perform laboratory activities for which they are responsible.

c) The laboratory has a process for managing competence of its personnel, that includes requirements for frequency of competence assessment.

d) The laboratory has documented information demonstrating competence of its personnel.

Ref: *IBTS/RCI/SOP/0028:*

6.2.3 Authorisation

The laboratory authorises personnel to perform specific laboratory activities including but not limited to the following:

a) Selection, development, modification, validation and verification of methods;

b) Review, release and reporting of results;

c) Use of laboratory information systems including accessing patient data & information, entering patient data and examination results, changing patient data or examination results.

Only staff who are trained and certified on procedures specific for these activities are authorised to perform these activities.

Ref: *IBTS/RCI/SOP/0028*
Ref: *IBTS/IT/SOP/0069*
Ref: *IBTS/IT/POL/0015*

6.2.4 Continuing education and professional development

A continuing education programme is available to personnel who participate in managerial and technical processes. All personnel participate in continuing education and regular professional development, or other professional liaison activities.

The suitability of the programme and activities are periodically reviewed.

Ref: *IBTS/RCI/SOP/0028*
Ref: *IBTS/RCI/SOP/0066*

6.2.5 Personnel records

The laboratory has procedures and retains records for the following:

a) determining the competence requirements specified in 6.2.2 a;
b) position descriptions;
c) the training, and re-training;
d) authorisation of personnel;
e) monitoring competence of personnel.

Refer to section 6.2.1-6.2.4 for relevant references.

6.3 Facilities and environmental conditions

6.3.1 General

The laboratory facilities and environmental conditions are suitable for laboratory activities and do not adversely affect the validity of results, or the safety of patients, visitors, laboratory users, and personnel.

This includes pre-examination related facilities and sites other than the main laboratory premises where examinations are performed.

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 (*IBTS/RCI/SOP/0084*)
- 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

6.3.2 Facility controls

Facility controls are implemented, recorded, monitored, periodically reviewed and include:

a) Control of access, taking into consideration safety, confidentiality, quality, and safeguarding medical information and patient samples.

b) Prevention of contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, ventilation, noise, water and waste disposal;

c) Prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation;

d) Provision of safety facilities and devices, where applicable, and regularly verifying their functioning;

e) Maintenance of laboratory facilities in a functional and reliable condition.

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.

Ref: *IBTS/FAC/SOP/0318*
Ref: *IBTS/IT/SOP/0069*
Ref: *IBTS/IT/POL/0015*
Ref: *IBTS/FAC/SOP/0328*
Ref: *IBTS/FAC/SOP/0302*
Ref: *IBTS/FAC/SOP/0306*
Ref: *RCI Laboratory Health and Safety Manual, Doc ID: 62.*
Ref: *IBTS/RCI/SOP/0019*

Ref: *IBTS/RCI/SOP/0047*
Ref: *IBTS/RCI/SOP/0084*
Ref: *IBTS/REES/SOP/0001*

6.3.3 Storage facilities

a) Storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents, and records is provided.

b) Patient samples and materials used in examination processes are stored in a manner that prevents contamination and deterioration.

c) Storage and disposal facilities for hazardous materials and biological waste is appropriate to the classification of the materials in the context of any statutory or regulatory requirements.

Ref: *IBTS/RCI/SOP/0050*
Ref: *IBTS/RCI/SOP/0030*
Ref: *IBTS/RCI/SOP/0084*

6.3.4 Personnel facilities

All staff have access to facilities within the NBC to ensure personnel safety, comfort and hygiene as described in *IBTS/QA/QM/0001*. These include but are not limited to:

- Toilet facilities
- Changing facilities including showering facilities
- Supply of drinking water
- Personal Lockers
- Storage area for personal protective equipment
- Meeting rooms
- Study areas
- Rest areas

6.3.5 Sample collection facilities

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

6.4 Equipment

6.4.1 General

The laboratory has processes in place for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, to ensure proper functioning and to prevent contamination or deterioration.

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

Ref: *IBTS/ADM/SOP/0001*
Ref: *IBTS/VAL/SOP/0006*
Ref: *IBTS/VAL/SOP/0009*
Ref: *IBTS/RCI/POL/0003*
Ref: *IBTS/RCI/SOP/0081*
Ref : IBTS/QA/SOP/0061

6.4.2 Equipment requirements

a) The laboratory has access to equipment required for the correct performance of laboratory activities.

b) There is no equipment in RCI that is used outside the laboratory's permanent control.

c) Each item of equipment that can influence laboratory activities are uniquely labelled, marked or otherwise identified and a register maintained.

d) The laboratory maintains and replaces equipment as needed to ensure the quality of examination results.

Ref: *IBTS/RCI/POL/0003*
Ref: *IBTS/VAL/SOP/0009*

6.4.3 Equipment acceptance procedure

The laboratory verifies that the equipment conforms to specified acceptability criteria before being placed or returned into service.

Equipment used for measurement is capable of achieving either the measurement accuracy or measurement uncertainty, or both, required to provide a valid result (See sections 7.3.3 and 7.3.4 for details)

The validation Department implements a Validation master plan, which requires that all new equipment be suitably validated prior to use. Records of all validations are maintained by the Validation Department

Ref: *IBTS/RCI/POL/0003*
Ref: *IBTS/QA/VMP/0001*
Ref: *IBTS/VAL/SOP/0008*

6.4.4 Equipment instructions for use

a) The laboratory has appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results. This is managed in individual equipment SOPs.

b) Equipment is operated by trained, authorised, and competent personnel (See section 6.2).

c) Instructions for the use of equipment, including those provided by the manufacturer, are readily available.

d) The equipment is used as specified by the manufacturer, unless validated by the laboratory (See Section 7.3.3).

Ref: *IBTS/RCI/POL/0003*

6.4.5 Equipment maintenance and repair

a) The laboratory has preventative maintenance programmes, based on manufacturer's instructions. The equipment schedule is maintained by the Validation Department in conjunction with RCI. Deviations from manufacturer's schedules or instructions are recorded.

b) Equipment is maintained in a safe working condition and working order. This includes examination of electrical safety, any emergency stop devices and the safe handling and disposal hazardous materials by authorised personnel.

c) Equipment that is defective or outside specified requirements, are taken out of service. It is clearly labelled or marked as being out of service, until it has been verified to perform correctly. The laboratory examines the effect of the defect or deviation from specified requirements and initiates actions when non-conforming work occurs.

d) Where applicable, the laboratory decontaminates equipment before service, repair or decommissioning, provides suitable space for repairs and provides appropriate personal protective equipment.

The validation department implements and maintains a Calibration and Maintenance masterplan, in conjunction with the RCI department, which

ensures that all equipment is maintained, calibrated and re-qualified to ensure fitness for use and maintenance of the validated state.

Ref : IBTS/QA/SOP/0061

Ref: *IBTS/VAL/SOP/0005*
Ref: *IBTS/QA/VMP/0006*
Ref: *IBTS/VAL/SOP/0008*
Ref: *IBTSS/VAL/SOP/0009*
Ref: *IBTS/RCI/SOP/0084*
Ref: *IBTS/RCI/POL/0003*

6.4.6 Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment are investigated and reported to either the manufacturer or the supplier, or both, and appropriate authorities as required.

The laboratory shall have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer.

Ref: *IBTS/QA/SOP/0068*
Ref: *IBTS/QA/SOP/0006*

6.4.7 Equipment Records

Records are maintained for each item of equipment that influences the results of laboratory activities. Records are maintained and readily available for a minimum of the lifespan of the equipment (See section 8.4.3). These records shall include the following, where relevant, at a minimum:

Record ID	Record Description	Record Location
a.	Identity of equipment	Q-Pulse Validation
	Manufacturer's name, equipment type, makes model and serial number.	Q-Pulse Validation
	Supplier / Manufacturer contact person and telephone number.	Validation Dept file.
b.	Date of receipt, acceptance testing and entering into service.	Validation Dept file.
c.	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.
	Evidence that equipment conforms with specified acceptability criteria	Validation Spreadsheets
d.	Current location.	Q-Pulse Validation
e.	Conditions when received e.g. new, used or reconditioned.	Validation Dept file.
f.	Manufacturer's instructions/ manual	Equipment validation documentation file
g.	Schedule for preventative maintenance	Q-Pulse Validation
h.	Maintenance activities performed by the lab or approved external service provider	Q-Pulse Validation
i.	Damage, malfunction, modification and repair	Q-Pulse Validation.
j.	Copies / reports / certs of calibrations Verifications including dates / times / results Adjustments Acceptance criteria and due date of next calibration / verification	Q-Pulse Validation
k.	Status of equipment such as active or in-service, out of service, quarantined, retired or obsolete	Q-Pulse Validation

6.5 Equipment calibration and metrological traceability

6.5.1 General

The laboratory has specified calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results. For quantitative methods of a measured analyte, specifications include calibration and metrological traceability requirements. Qualitative methods and quantitative methods that measure characteristics rather than discrete analyses specify the characteristic being assessed and such requirements necessary for reproducibility over time.

The validation department implements and maintains a Calibration and maintenance masterplan, in conjunction with the RCI department, which ensures that all equipment is maintained, calibrated and re-qualified to ensure fitness for use and maintenance of the validated state.

Ref*:* *IBTS/RCI/POL/0003*
Ref: *IBTS/VAL/SOP/0008*
Ref: *IBTS/QA/VMP/0006*

6.5.2 Equipment calibration

The laboratory has procedures for the calibration of equipment that directly or indirectly affects examination results. These specify:

a) conditions of use and the manufacturers' instructions for calibration;

b) recording the metrological traceability;

c) verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;

d) recording the calibration status and date of re-calibration;

e) ensuring that, where correction factors are used, these are updated and recorded when re-calibration occurs;

f) handling of situations when calibration was out of control, to minimise risk to service operation and to patients.

Ref: *IBTS/VAL/SOP/0008*

6.5.3 Metrological traceability of measurement results

a) The laboratory establishes and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

b) The laboratory ensures that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through:
   - calibration by a competent producer; or
   - certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI.

c) Where it is not possible or relevant to provide traceability, according to 6.5.3a), other means for providing confidence in the results shall be applied, including but not limited to the following:

   - results of reference measurement procedures, specified methods or consensus standards, that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison;
   - measurement of calibration by another procedure;

d) For genetic examinations, traceability to genetic reference sequences shall be established. This is not applicable to RCI.

e) For qualitative methods, traceability may be demonstrated by testing of known material or previous samples sufficient to show consistent identification and, when applicable, intensity of reaction.

Ref: *IBTS/QA/VMP/0006*
Ref: *IBTS/VAL/SOP/0008*

6.6 Reagents and consumables

6.6.1 General

The RCI laboratory has processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables.

Ref: *IBTS/RCI/SOP/0030*

Ref: *IBTS/RCI/SOP/0046*
Ref: *IBTS/RCI/SOP/0054*
Ref: *IBTS/RCI/SOP/0049*

6.6.2 Reagents and consumables – Receipt and storage

The laboratory stores reagents and consumables according to manufacturers' specifications and monitors the environmental conditions where relevant.

When the laboratory is not the receiving facility, it verifies that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.

Reagents and consumables may be received either into the Stores Department, or directly into the RCI Laboratory itself.

Ref: *IBTS/ADM/SOP/0002*

6.6.3 Reagents and consumables – Acceptance testing

Each reagent or new formulation of examination kits with changes in reagents/ procedure or a new lot or shipment are verified for performance before placing into use, or before release of results, as appropriate.

Consumables that can affect the quality of examinations are verified for performance before use in examinations.

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.

The RCI laboratory delegates the responsibility of batch acceptance of reagents, red cell panels and materials utilised in the RCI laboratory to the Materials Management department with the exception of batch acceptance of antisera on the automated analyser.

Ref*: IBTS/RCI/POL/0004*
Ref: *IBTS/QA/SOP/0006*
Ref: *IBTS/RCI/SOP/0081*
Ref: *IBTS/MM/SOP/0004*
Ref: *IBTS/MM/SOP/0006*
Ref: *IBTS/MM/SOP/0010*
Ref: *IBTS/MM/SOP/0015*
Ref: *IBTS/MM/SOP/0016*
Ref: *IBTS/MM/SOP/0019*
Ref*: IBTS/MM/SOP/0036*

6.6.4 Reagents and consumables – Inventory management

The RCI Laboratory has an established inventory management system for reagents and consumables.

The system for inventory management segregates reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use.

Ref: *IBTS/RCI/SOP/0030*

6.6.5 Reagents and consumables – Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers, are readily available. Reagents and consumables are used according to the manufacturer's specifications. If they are intended to be used for other purposes, see Section 7.3.3.

Ref: *IBTS/MM/SOP/0004*
Ref: *IBTS/MM/SOP/0006*
Ref: *IBTS/MM/SOP/0010*
Ref: *IBTS/MM/SOP/0015*
Ref: *IBTS/MM/SOP/0016*
Ref: *IBTS/MM/SOP/0019*
Ref*: IBTS/MM/SOP/0036*

6.6.6 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 either the manufacturer or the supplier, or both, and appropriate authorities as required.

The laboratory shall have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer.

Ref: *IBTS/QA/SOP/0068*
Ref*: IBTS/QA/SOP/0006*

6.6.7 Reagents and consumables – Records

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

a) identity of the reagent or consumable;

b) manufacturer's information, including instructions, name and batch code or lot number;

c) date of receipt and condition when received, the expiry date, date of first use, and where applicable, the date the reagent or consumable was taken out of service;

d) records that confirm the reagent's or consumables initial and ongoing acceptance for use.

Where the laboratory uses reagents prepared, resuspended or combined in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking the preparation, as well as the dates of preparation and expiry.

Ref: *IBTS/RCI/SOP/0030*
Ref*: IBTS/RCI/SOP/0049*
Ref: *IBTS/ADM/SOP/0002*
Ref: *IBTS/MM/SOP/0004*
Ref: *IBTS/MM/SOP/0006*
Ref: *IBTS/MM/SOP/0010*
Ref: *IBTS/MM/SOP/0015*
Ref: *IBTS/MM/SOP/0016*
Ref: *IBTS/MM/SOP/0019*
Ref: *IBTS/MM/SOP/0036*

6.7 Service agreements

6.7.1 Agreements with laboratory users

The laboratory has a procedure to establish and periodically review agreements for providing laboratory activities. The procedure ensures that:

a) the requirements are adequately specified;

b) the laboratory has the capability and resources to meet the requirements;

c) when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants.

Laboratory users shall be informed of any changes to an agreement that can affect examination results.

Records of reviews including any significant changes are retained.

IBTS enters 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.

Ref: *IBTS/DSP/SOP/0051*
Ref*: IBTS/ADM/POL/0001*
Ref: *IBTS/ADM/SOP/0003*

6.7.2 Agreements with POCT operators

The RCI laboratory does not provide services to POCT operators.

6.8 Externally Provided Products and Services

6.8.1 General

The laboratory ensures that externally provided products and services that affect laboratory activities are suitable when such products and services are:

a) intended for incorporation into the laboratory's own activities;

b) provided, in part or in full, directly to the user by the laboratory, as received from an external provider;

c) used to support the operation of the laboratory.

Ref: *IBTS/ADM/SOP/0003*
Ref: *IBTS/RCI/SOP/0013*

6.8.2 Referral laboratories and consultants

The laboratory shall communicate its requirements to referral laboratories and consultants who provide interpretations and advice, for:

a) the procedures, examinations, reports and consulting activities to be provided;
b) management of critical results;

c) any required personnel qualifications and demonstration of competence.

Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) is responsible for ensuring that examination result of the referral laboratory are provided to the person making the request.

A list of all referral laboratories and consultants is maintained.

Ref: *IBTS/RCI/SOP/0013*
Ref: *IBTS/RCI/CM/0001*

6.8.3 Review and approval of externally provided products and services

The laboratory has procedures and retains records for:

a) defining, reviewing and approving the laboratory's requirements for all externally provided products and services;

b) defining criterial for qualification, selection, evaluation of performance and re-evaluation of external providers;

c) referral of samples;

d) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user;

e) taking any actions arising from evaluations of the performance of external providers.

Ref: *IBTS/RCI/SOP/0013*
Ref: *IBTS/ADM/SOP/0003*
Ref: *IBTS/RCI/SOP/0066*
Ref: *IBTS/RCI/LIST/0002*

7 PROCESS REQUIREMENTS

7.1 General

The RCI laboratory identifies potential risks to patient care in the pre-examination, examination and post-examination processes. These risks are assessed and mitigated to the extent possible. The residual risk is communicated to user as appropriate.

The identified risks and effectiveness of the mitigation processes is monitored and evaluated according to the potential harm to the patient (See Section 5.6).

The laboratory also identifies opportunities to improve patient care and develop a framework to manage these opportunities (See Section 8.5).

Ref: IBTS/RCI/CM/0001
Ref: IBTS/RCI/SOP/0080

7.2 Pre-examination processes

7.2.1 General

The Laboratory has procedures in place for all relevant pre-examination activities and makes them accessible to relevant personnel.

7.2.2 Laboratory information for patients and users

The RCI Laboratory provides information for patients and users of the laboratory services in *IBTS/RCI/CM/0001*. The information is sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements. The information provided includes, as appropriate:

a) the location of the laboratory, operating hours and contact information;

b) the procedure for requesting and the collection of samples;

c) the scope of the laboratory activities and time for expected availability of results;

d) the availability of advisory services;

e) requirements for patient consent;

f) factors known to significantly impact the performance of the examination or the interpretation of the results;

g) the laboratory complaints procedure

Note: As RCI acts as a referral laboratory, requirements for patient consent is the responsibility of the service requester.

7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

a) Each request accepted by the laboratory for examination(s) is considered an agreement. All samples received by RCI for examination must be accompanied by the appropriate official RCI Request form BT – 0345 or BT - 0007.

b) The examination request must provide sufficient information to ensure:
   - unequivocal traceability of the patient to the request and sample;
   - identity and contact information of requester;
   - identification of the examination(s) requested;
   - informed clinical and technical advice, and clinical interpretation can be provided.

   Specimen and request form acceptance criteria are outlined in *IBTS/RCI/CM/0001*

c) The examination request information is provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user. The format of the request form (paper) and the method by which examination requests are communicated to the RCI Laboratory are determined in discussion with the service users and through review.

d) Where necessary for patient care, the laboratory will communicate with users or their representatives, to clarify the user's request.

   Ref: *IBTS/RCI/SOP/0003*
   Ref: *IBTS/RCI/SOP/0066*

7.2.3.2 Oral requests

The laboratory has a procedure for managing oral requests for examinations. This includes the provision of documented confirmation of the examination request to the laboratory, within a given time. Refer to Section 7.2.6.1.

Ref: *IBTS/RCI/CM/0001*
Ref: I*BTS/RCI/SOP/0003*

7.2.4 Primary sample collection and handling

7.2.4.1 General

The laboratory has documented procedures for the collection and handling of primary samples. This information is available to those responsible for sample collection in *IBTS/RCI/CM/0001*

Any deviation from the established collection procedures is clearly recorded. The potential risk and impact on the patient outcome of acceptance or rejection of the sample shall be assessed, recorded and is communicated to the appropriate personnel. See Section 7.2.6.2.

Ref: *IBTS/RCI/CM/0001*
Ref: *IBTS/RCI/RL/0001_2*

The laboratory periodically reviews requirements for sample volume, collection device and preservatives for all sample types to ensure that neither insufficient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte.

Ref*: IBTS/RCI/CM/0001*
Ref: *IBTS/RCI/SOP/0066*

7.2.4.2 Information for pre-collection activities

The laboratory provides information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised. This includes:

a) preparation of the patient (Provided by requesting hospital, not covered by IBTS);

b) type and amount of the primary sample to be collected with descriptions of the containers and any necessary additives;

c) special timing of collection, where needed;

d) provision of clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs);

e) sample labelling for unequivocal identification of the patient, as well as source and site of sample, and labelling when several samples from the same patient are to be collected;

f) the laboratory's criteria for the acceptance and rejection of samples specific to the examinations requested.

Ref: *IBTS/RCI/CM/0001*

7.2.4.3 Patient consent

Patient consent for tests required in the RCI laboratory, is the responsibility of the service requestor.

Ref: *IBTS/RCI/CM/0001*

7.2.4.4 Instructions for collection activities

Collection activities do not take place in the IBTS. However, to ensure safe, accurate and clinically appropriate sample collection and pre-examination storage, the laboratory provides instructions for:

a) verification of the identity of the patient from whom a primary sample is collected;

b) verification, and where relevant, recording 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];

c) collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant;

d) instructions for labeling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;

e) recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;

f) requirements for separating or dividing the primary sample when necessary;

g) stabilisation and proper storage conditions before collected samples are delivered to the laboratory;

h) safe disposal of materials used in the collection.

Ref: *IBTS/RCI/CM/0001*

7.2.5 Sample transportation

a) Transportation of samples to the RCI laboratory is the responsibility of the service requestor. However, to ensure timely and safe transportation of samples, the laboratory provides instructions for:

   1) packaging of samples for transportation;
   2) ensuring time between collection and receipt in the laboratory is appropriate for the requested examinations;

   3) any specific requirements to ensure integrity of samples e.g. use of designated preservatives.

   Note: There is no requirement to maintain temperature interval specified for sample collection and handling for RCI specimens.

b) If it has been identified that the integrity of a sample has been compromised and there is a health risk, e.g. sample leaking on receipt, the referring hospital is notified immediately so actions can be taken by the referring hospital to minimise the risk and prevent recurrence.

c) As sample transportation systems are the responsibility of the service requester, periodic evaluation of the adequacy of the sample transportation is the responsibility of the service requester.

   Ref: *IBTS/RCI/CM/0001*
   Ref: IBTS/RCI/SOP/0003

7.2.6 Sample receipt

7.2.6.1 Sample receipt procedure

The laboratory has a procedure in place for sample receipt that includes:

a) the unequivocal traceability of samples by request and labelling, to a uniquely identified patient;

b) criteria for acceptance or rejection of samples;

c) recording the date and time of receipt of the sample;

d) recording the identity of the person receiving the sample;

e) evaluation of received samples, by authorised personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s);

f) instructions for samples specifically marked as urgent, which include detail of special labelling, transport, any rapid processing method, turn around times, and special reporting criteria to be followed;

g) ensuring that all portions of the sample are unequivocally traceable to the original sample.

It is RCI policy to have a request form for every requested test. Where a sample is already available in the laboratory, is still valid for testing, and a verbal test is received, testing may commence prior to receipt of the request form.

The lack of a request form does not delay the processing of an urgent request for additional examination. Verbal requests for RCI are recorded and testing can commence. A completed request form is requested for all additional requests.

Ref: *IBTS/RCI/CM/0001*
Ref: *IBTS/FAC/SOP/0324*
Ref: *IBTS/RCI/SOP/0003:*
Ref: *IBTS/RCI/SOP/0001*
Ref: *IBTS/RCI/SOP/0077*

7.2.6.2 Sample acceptance exceptions

a) The laboratory has a process that considers the best interests of the patient in receiving care, when a sample has been compromised, including;
   1) incorrect patient or sample identification,
   2) sample instability due to, for example, delay in transport,
   3) incorrect storage or handling temperature,
   4) inappropriate container(s), and
   5) insufficient sample volume.

b) When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report will indicate the nature of the problem and, where applicable, advise caution when interpreting results that can be affected.

Ref: *IBTS/RCI/CM/0001*
Ref: *IBTS/RCI/SOP/0003*
Ref: *IBTS/RCI/SOP/0002*
Ref: *IBTS/RCI/RL/0001_2*

7.2.7 Pre-examination handling, preparation and storage

7.2.7.1 Sample protection

The laboratory has procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during handling, preparation, and storage (See Section 6.3).

7.2.7.2 Criteria for additional examination requests

Laboratory procedures includes time limits for requesting additional examinations on the same sample.

Ref: *IBTS/RCI/CM/0001*
Ref: *IBTS/RCI/SOP/0003*

7.2.7.3 Sample Stability

Considering the stability of the analyte in a primary sample, the time between sample collection and performing the examination is specified and monitored where relevant.

Ref: *IBTS/RCI/CM/0001*
Ref: *IBTS/RCI/SOP/0003*
Ref: *IBTS/RCI/SOP/0076*

7.3 Examination Processes

7.3.1 General

a) The laboratory selects and uses examination procedures which have been validated for their intended use to assure the clinical accuracy of the examination for patient testing. These procedures are in widespread use and have been published or referenced in authoritative textbooks and journals.

b) The performance specifications for each procedure relate to the intended use of that procedure and its impact on patient care.

c) All procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activity, are kept up to date and readily available to personnel.

d) All personnel performing the examinations are trained in the relevant procedures, and follow established procedures, and the identity of personnel performing significant activities in the examination processes are recorded.

e) The examination methods are evaluated periodically by authorised personnel to ensure they are clinically appropriate for the requests received.

Ref: IBTS/RCI/SOP/0081
Ref: IBTS/QA/POL/0002
Ref: IBTS/QA/SOP/0161

7.3.2 Verification of examination methods

a) The laboratory has a procedure to verify that it can properly perform examination methods before introducing into use, by ensuring that the required performance, as specified by the manufacturer or method can be achieved.

b) The performance specifications for the examination method confirmed during the verification process are relevant to the intended use of the examination results.

c) The laboratory ensures the extent of the verification of examination methods is sufficient to ensure validity of results pertinent to clinical decision making.

d) Personnel with the appropriate authorisation and competence review the verification results and record whether the results meet the specified requirements.

e) If a method is revised by the issuing body, the laboratory repeats the verification to the extent necessary.

f) Verification records include the following:
   1) performance Specifications to be achieved
   2) results of verification
   3) statement on whether performance specifications were met or if not, actions taken.

Ref: IBTS/RCI/SOP/0081
Ref: IBTS/QA/SOP/0006

7.3.3 Validation of examination methods

a) The laboratory validates examination procedures derived from the following sources:
   1) laboratory designed or developed methods;

2) methods used outside their intended scope (i.e. outside of the manufacturer's instructions for use, or original validated measurement range; third party reagents used on instruments other than intended instruments and where no validation data is available);

3) validated methods subsequently modified

b) The validation will be as extensive as is necessary and confirm, through the provision of objective evidence in the form of performance specifications, that the specific requirements for the intended use of the examination have been fulfilled. The laboratory ensures that the extent of the validation of an examination method is sufficient to ensure the validity of results pertinent to clinical decision making.

c) Personnel with the appropriate authorisation and competence review the validation results and record whether the results meet the specified requirements.

d) When changes are proposed to a validated examination procedure, the clinical impact is reviewed, and a decision made as to whether to implement the modified method.

e) The following records of validation, at a minimum, are retained:
   1) Validation procedure used;
   2) Specific requirements for the intended use;
   3) Determination of the performance specifications of the method;
   4) Results obtained;
   5) Statement on the validity of the method, detailing its fitness for the intended use.

Ref: *IBTS/QA/VMP/0001*
Ref: *IBTS/VAL/SOP/0001*
Ref: *IBTS/RCI/SOP/0081*
Ref: *IBTS/QA/SOP/0006*

7.3.4 Evaluation of measurement uncertainty (MU)

For RCI laboratory testing results that 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. For RCI laboratory testing result that are quantitative in nature, the procedure for establishing and reviewing the uncertainty of measurement is outlined in *IBTS/RCI/SOP/0086*

a) The MU of measured quantity values is evaluated and maintained for its intended use, where relevant. The MU is compared against performance specifications and documented.

b) MU evaluations are regularly reviewed.

c) For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU estimation is documented.

d) MU information is readily available to laboratory users on request.

e) When users have inquiries on MU, the laboratory's response takes into account other sources of uncertainty, such as, but not limited to biological variation.

f) If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative, based on a threshold, MU in the output quantity shall be estimated using representative positive and negative samples.

g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process.

h) MU should be taken into consideration when performing verification or validation of a method when relevant.

Ref: IBTS/RCI/SOP/0086

7.3.5 Biological reference intervals and clinical decision limits

Biological reference intervals and clinical decision limits, when needed for interpretation of examination results, are defined and communicated to users.

a) Biological reference intervals and clinical decision limits are defined and their basis recorded to reflect the patient population served by the laboratory, while considering the risk to patients.

b) Biological reference intervals and clinical decision limits are periodically reviewed, and any changes communicated to users.

c) When changes are made to an examination or pre-examination method, the laboratory reviews the impact on associated biological reference intervals and clinical decision limits and communicates to the users when applicable.

d) For examinations that identify presence or absence of a characteristic, the biological reference interval is the characteristic to be identified, e.g. presence of an antibody.

Ref: *IBTS/RCI/CM/0001*
Ref: *IBTS/QA/SOP/0006*
Ref: *IBTS/RCI/SOP/0066*

7.3.6 Documentation of examination procedures

a) The laboratory documents its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results.

b) Procedures are written in a language understood by laboratory personnel and are available in appropriate locations.

c) Any abbreviated document contents correspond to the procedure.

d) Information from product instructions for use, that contain sufficient information, can be incorporated into procedures by reference.

e) When the laboratory makes a validated change to an examination procedure which could affect interpretation of results, the implications of this are explained to the users.

f) All documents associated with the examination process are subject to document control (See Section 8.3).

Ref: *IBTS/QA/POL/0002*
Ref: *IBTS/QA/SOP/0143*
Ref: *IBTS/QA/SOP/0006*

7.3.7 Ensuring the validity of examination results

7.3.7.1 General

The laboratory has procedures for monitoring the validity of results. The resulting data is recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed.

Ref: *IBTS/RCI/SOP/0089*

7.3.7.2 Internal quality control (IQC)

a) The laboratory has IQC procedures for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making.

   1) The intended clinical application of the examination is considered, as the performance specifications for the same measurement can differ in different clinical settings.

   2) The procedure allows for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure avoids lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both, where applicable.

   3) The use of third party IQC material is considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer.

b) The laboratory selects IQC material that is fit for its intended purpose. When selecting IQC material, the following factors are considered:

   1) stability with regard to the properties of interest;

   2) the matrix is as close as possible to that of patient samples;

   3) the IQC material reacts to the examination method in a manner as close as possible to patient samples;

   4) the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.

c) If appropriate IQC material is not available, the laboratory considers the use of other methods of IQC. Examples of other such methods may include:

   1) trend analysis of patient results e.g. with moving average of patient results, or percentage of samples with results below or above certain values or associated with a diagnosis;

   2) comparison of results for patient samples on a specified schedule to results for patient samples examined by an alternative procedure

validated to have its calibration metrologically traceable to the same or higher order reference as specified as ISO 17511;

3) retest of retained patient samples.

d) IQC is performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result.

e) The resulting data is recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques are applied to review the results.

f) IQC data is reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance.

g) The laboratory prevents the release of patient results in the event that IQC fails the defined acceptability criteria.

1) When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, the results are rejected, and relevant patient samples re-examined after the error has been corrected (See Section 7.5).

2) The results from patient samples that were examined after the last successful IQC event are evaluated.

Ref: *IBTS/RCI/SOP/0089*

7.3.7.3 External quality assessment (EQA)

a) The laboratory monitors its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results.

b) The laboratory has a procedure for EQA enrolment, participation and performance for examination methods used, where such programmes are available.

c) EQA samples are processed by personnel who routinely perform pre-examination, examination and post-examination procedures.

d) The EQA programmes selected, to the extent possible:

1) have the effect of checking pre-examination, examination, and post-examination processes;

2) provide samples that mimic patient samples for clinically relevant challenges;

e) When selecting EQA programmes, the lab considers the type of target value offered. Target values are:

1) independently set by a reference method, or

2) set by overall consensus data, and/or

3) set by method peer group consensus data, or

4) set by a panel of experts.

f) When an EQA programme is either not available, or not considered suitable, the lab uses alternative methodologies to monitor examination method performance. This rational for the chosen alternative is justified and evidence of its effectiveness is provided.

Alternatives utilised are:

1) The RCI laboratory participates in inter laboratory comparison schemes. These ILC schemes evaluates the individual laboratory IQC results against pooled results from participants using the same material. These are only utilised when there are no external quality assurance programme is available to monitor the examination method performance.

g) EQA data is reviewed at regular intervals with specified acceptability criteria in a time frame which allows for a meaningful indication of current performance.

h) Where EQA results fall outside specified acceptability criteria, appropriate actions are taken (See Section 8.7), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.

i) Where it is determines that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment is considered and users advised as appropriate.

Ref: *IBTS/RCI/SOP/0061*
Ref: *IBTS/QA/SOP/0068*
Ref: *IBTS/RCI/SOP/0076*

7.3.7.4 Comparability of examination results

a) When either different methods or equipment, or both are used for an examination, and/or the examination is performed at different sites, a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals shall be specified.

b) The laboratory records the results of comparability performed and its acceptability.

c) The laboratory periodically reviews the comparability of results.

d) Where differences are identified, the impact of those differences on biological reference intervals and clinical decision limits is evaluated and acted upon.

e) The laboratory informs users of any clinically significant differences in comparability of results.

Ref: *IBTS/RCI/SOP/0089*
Ref: *IBTS/QA/SOP/0068*

7.4 Post examination processes

7.4.1 Reporting of results

7.4.1.1 General

a) The laboratory examination results are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure. The report includes all available information necessary for the interpretation of the results.

b) The laboratory has a procedure to notify users when examination results are delayed, based on the impact of the delay on the patient.

c) All information associated with issued reports is retained in accordance with management system requirements (See 8.4).

Ref: IBTS/RCI/SOP/0002
Ref: *IBTS/QA/SS/0453*
Ref: *IBTS/DP/POL/0002*
Ref: *IBTS/RCI/SOP/0050*
Ref: *IBTS/RCI/SOP/0088*

7.4.1.2 Result review and release

Results are reviewed and authorised prior to release.

The RCI laboratory ensures that authorised personnel review the results of examinations and evaluate them against IQC and, as appropriate, available clinical information and previous examination results.

Responsibilities and procedures for how examination results are released for reporting, including by whom and to whom, are specified.

Ref: IBTS/RCI/SOP/0002

7.4.1.3 Critical result reports

When examination results fall within established critical decision limits;

a) the user or other authorised person is notified as soon as relevant, based on clinical information available;

b) actions taken are documented including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication and any difficulties encountered in notification;

c) the laboratory has an escalation procedure for laboratory personnel when a responsible person cannot be contacted.

Ref: IBTS/RCI/SOP/0002
Ref: IBTS/MED/SOP/0063

7.4.1.4 Special considerations for results

a) When agreed with the user, the results may be reported in a simplified way. Any information listed in 7.4.1.6 and 7.4.1.7 that is not reported to the user is readily available.

b) When results are transmitted as an interim or preliminary report the final report is always forwarded to the user.

c) Records are kept of all results which are provided orally, including details of verification of accuracy of communication, as in 7.4.1.3 b). Such results are always followed by a report.

d) Special counselling may be needed for examination results with serious implications for the patient (e.g. for genetic or certain infectious diseases). Laboratory management ensure that results are not communicated directly to the patient. It is the responsibility of the staff in the referring hospital to ensure that any result obtain from the RCI laboratory is communicated in the appropriate manner to the patient and that counselling is provided to the patient if required.

e) Results of laboratory examinations that have been anonymised may be used for such purposes as epidemiology, demography, or other statistical analyses, provided that all risks to patient privacy and confidentiality are mitigated and in accordance with any either legal or regulatory requirements, or both.

Ref: IBTS/RCI/SOP/0002
Ref: IBTS/MED/SOP/0063

7.4.1.5 Automated selection, review, release and reporting of results

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

7.4.1.6 Requirements for reports

Each report contains the following information:

a) unique patient identification, the date of primary sample collection, and the date of the issue of the report, on each page of the report;

b) identification of the RCI Laboratory which issued the report;

c) name or unique identifier of the user;

d) type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description);

e) clear, unambiguous identification of the examinations performed;

f) identification of the examination method used, where relevant, including, where possible and necessary, harmonised (electronic) identification of the measurand and measurement principle;

g) examination results with, where appropriate, the units of measurement reported in SI units, units traceable to SI units, or other applicable units;

h) biological reference intervals, clinical decision values, likelihood ratios or diagrams/nomograms supporting clinical decision values, where relevant;

i) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;

j) identification of the person(s) reviewing the results and authorising the release of the report;

k) identification of any results that need to be considered as preliminary;

l) indications of any critical results;

m) unique identification of all its components are recognised as a portion of a complete report and a clear identification of the end (e.g. page number to total number of pages).

7.4.1.7 Additional information for reports

a) When necessary for patient care, the time of the primary sample collection is included.

b) Time of release of report.

c) Identification of all examinations or part of examinations performed by a referral laboratory, including information provided by consultants, without alteration, as well as the name of the laboratory performing the examinations.

d) When applicable, a report includes interpretation of results and comments on:

1) sample quality and suitability that can compromise the clinical value of examination results;

2) discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations;

3) possible risk of misinterpretation when different units of measurement are in use regionally or nationally;

4) result trends or significant changes over time.

Ref: IBTS/RCI/SOP/0002

7.4.1.8 Amendments to reported results

Procedures for the issue of amended or revised results ensure that:

a) The reason for the change is recorded and included in the revised report, when relevant.

b) Revised results are delivered in the form of an additional document or data transfer, and clearly identified as having been revised, and the date and the patient's identity of the original report is indicated.

c) The user is made aware of the revision.

d) When it is necessary to issue a completely new report, this shall be uniquely identified and shall contain a reference and traceability to the original report that it replaces.

e) When the reporting system cannot capture revisions, a record of such shall be kept.

Ref: IBTS/RCI/SOP/0002

7.4.2 Post-examination handling of samples

The laboratory specifies the length of time samples are to be retained following examination and the conditions under which samples are stored.

The laboratory ensures that after the examination, the

a) patient and source identification of the sample are maintained,

b) suitability of the sample for additional examinations is known,

c) sample is stored in a manner that optimally preserves suitability for additional examinations,

d) samples can be located and retrieved, and

e) sample is discarded appropriately.

Ref*: IBTS/RCI/SOP/0050*
Ref: *IBTS/RCI/SOP/0084*
Ref: *RCI Laboratory Safety Manual, Doc ID: 62*

7.5 Nonconforming work

The laboratory has a process for when any aspect of its laboratory activities or examination results do not conform to its own procedures, quality specifications, or the user requirements. The process ensures that:

a) the responsibilities and authorities for the management of nonconforming work are specified;

b) immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory;

c) examinations are halted, and reports withheld when there is a risk of harm to patients;

d) an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been preleased prior to identification of the nonconformance;

e) a decision is made on the acceptability of the nonconforming work;

f) when necessary, examination results are revised, and the user is notified;

g) the responsibility for authorising the resumption of work is specified.

The laboratory implements corrective actions commensurate with the risk of recurrence of the nonconforming work (See Section 8.7).

The laboratory retains records of nonconforming work and actions specified in 7.5 a) to g).

Ref: *IBTS/QA/SOP/0068*

7.6 Control of data and information management

7.6.1 General

The laboratory has access to the data and information needed to perform laboratory activities.

The Laboratory information system in use in the RCI laboratory is eTraceline. Ancillary systems within the Laboratory include:

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

There is a procedure in place to describe the use laboratory information system (LIS). Examinations performed in the laboratory are logged on eTraceline and electronic reports are stored indefinitely on the system. The laboratory follows procedures to ensure that the confidentiality of patient information is maintained at all times.

Ref: *IBTS/LABPT/UG/0001*
Ref: *IBTS/LABT/UG/0001*
Ref: *IBTS/QA/POL/0002*
Ref: *IBTS/REES/SOP/0001*
Ref: *IBTS/DP/POL/0001*

7.6.2 Authorities and responsibilities for information management

The IBTS ensures that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and modification to the information system(s) that can affect patient care. The laboratory is ultimately responsible for the laboratory information systems.

Ref: *IBTS/IT/QM/0001*
Ref: *IBTS/QA/SS/0453*

7.6.3 Information systems management

The LIS used is in compliance with national and international requirements regarding data protection with reference to *IBTS/DP/POL/0001*
It is used for the collection, processing, recording, reporting, storage or retrieval of examination data and information, and is:

a) validated by the supplier and verified for functioning by the laboratory before introduction. Any changes to the system, including laboratory software configuration or modification to commercial off-the-shelf software, is authorised, documented and validated before implementation;

b) documented, and the documentation readily available to authorised users, including that for day to day functioning of the system;

c) implemented taking cyber security into account, to protect from unauthorised access and safeguard data against tampering or loss;

d) 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;

e) 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.

Calculations and data transfers are checked in an appropriate and systematic manner.

Ref: *IBTS/QA/VMP/0001*
Ref: *IBTS/LABPT/UG/0001*
Ref: *IBTS/LABT/UG/0001*
Ref: *IBTS/RCI/SOP/0002*
Ref: IBTS/RCI/SOP/0063
Ref: IBTS/IT/POL/0018
Ref: *IBTS/IT/SOP/0069*

7.6.4 Downtime plans

The laboratory has planned processes to maintain operations in the event of failure or during downtime in information systems that affect the laboratory's activities. There is no automated selection and reporting of results in the RCI Laboratory.
Ref: *IBTS/RCI/SOP/0063*

7.6.5 Off-site management

When the laboratory information system(s) are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements.

7.7 Complaints

7.7.1 Process

The laboratory follows a process for handling complaints. This process includes at least the following:

a) a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response;

b) tracking and recording the complaint, including the actions undertaken to resolve it;

c) ensuring appropriate actions are taken.

A description of the process for handling complains is publicly available.

Ref: *IBTS/QA/SOP/0063*

7.7.2 Receipt of complaint

a) Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, will resolve the complaint (See Section 8.7.1).

b) The laboratory receiving the complaint is responsible for gathering all necessary information to determine whether the complaint is substantiated.

c) Whenever possible the laboratory acknowledges receipt of the complaint and provide the complainant with the outcome and, if applicable, progress reports.

Ref: *IBTS/QA/SOP/0063*

7.7.3 Resolution of complaints

Investigation and resolution of complaints will not result in any discriminatory actions.

The resolution of complaints will be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach does not compromise impartiality.

Ref: *IBTS/QA/SOP/0063*

7.8 Continuity and emergency preparedness planning

The laboratory ensures that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified and a coordinated strategy exists that involves plans, procedures and technical measures to enable continues operations after a disruption.

Plans are periodically tested and the planned response capability exercised, where practicable.

The laboratory:

a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel;

b) provide information and training as appropriate to relevant laboratory personnel;

c) respond to actual emergency situations;

d) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact.

Ref: *IBTS/RCI/SOP/0063*
Ref: *IBTS/RR/BCP/0003*
Ref: *IBTS/RR/BCP/0006*
Ref: *IBTS/RR/SOP/0004*
Ref: *IBTS/RR/POL/0003*
Ref: *IBTS/RCI/SOP/0013*

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 General Requirements

8.1.1 General

The RCI laboratory in conjunction with the IBTS Quality Management System establishes, documents, implements, and maintains a management system.

The management system of the laboratory includes the following:

- Responsibilities (Section 8.1)
- Objectives and Policies (Section 8.2)
- Documented information (Section 8.2, 8.3 and 8.4)
- Actions to address risks and opportunities for improvement (Section 8.5)
- Continual improvement (Section 8.6)
- Corrective actions (Section 8.7)
- Evaluations and internal audits (Section 8.8)
- Management reviews (Section 8.9)

8.1.2 Fulfilment of management system requirements

The overarching IBTS Quality Management system meets the requirements outlined in Section 8.1.1 by establishing, implementing, and maintaining a quality management system. This quality management system supports and demonstrates the consistent fulfilment of the requirements of Clauses 4 to 7, and the requirements specified in 8.2 to 8.9. The IBTS Quality Management system is described in *IBTS/QA/QM/*0001. The RCI laboratory operates within the IBTS Quality Management system. The RCIs management of the quality management system is outlined in this document (IBTS/RCI/LM/0001).

Ref: *IBTS/QA/QM/0001:*
Ref: *IBTS/RCI/LM/0001:*

8.1.3 Management system awareness

The laboratory ensures that persons doing work under the laboratory's control are aware of:

a) relevant objectives and policies;

b) their contribution to the effectiveness of the management system, including the benefits of the improved performance;
c) the consequences of not conforming with the management system requirements.

Ref: *IBTS/QA/QM/0001:*
Ref: *IBTS/RCI/LM/0001:*

Ref: *IBTS/RCI/SOP/0066:*

8.2 Management system documentation

8.2.1 General

Laboratory management establishes, documents and maintains objectives and policies for the fulfilment of the purpose of this document, and ensures that the objectives and policies are acknowledged and implemented at all levels of the laboratory organisation.

8.2.2 Competence and quality

The objectives and policies address the competence, quality and consistent operation of the laboratory.

Ref: *IBTS/QA/QM/0001:*
Ref: *IBTS/RCI/LM/0001:*
Ref: IBTS/QA/SOP/0148:
Ref: *IBTS/RCI/SOP/0028:*

8.2.3 Evidence of commitment

Laboratory management shall provide evidence of commitment to the development and implementation of the management system to continually improve its effectiveness.

Ref: *IBTS/QA/QM/0001:*
Ref: *IBTS/RCI/LM/0001:*
Ref: *IBTS/RCI/SOP/0066:*

8.2.4 Documentation

All documentation, processes, systems, and records, related to the fulfilment of the requirements of this document are included in, references from, or linked to the management system.

Ref: *IBTS/QA/POL/0002:*
Ref: *IBTS/RCI/SOP/0088*

8.2.5 Personnel access

All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

Ref: *IBTS/QA/UG/0001*
Ref: *IBTS/QA/SOP/0088*

8.3 Control of management system documents

8.3.1 General

The laboratory controls the document (internal and external) that relate to the fulfilment of this document.

Ref: *IBTS/QA/POL/0002*
Ref: *IBTS/QA/SOP/0143*
Ref: *IBTS/QA/SOP/0161*
Ref: *IBTS/RCI/SOP/0088*

8.3.2 Control of Documents

The laboratory has procedures to ensure that:

a) documents are uniquely identified;
b) documents are approved for adequacy before issue by authorised personnel who have the expertise and competence to determine adequacy;

c) documents are periodically reviewed and updated as necessary;

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) changes and the current revision status of documents are identified;

f) documents are protected from unauthorised changes and any deletion or removal;

g) documents are protected from unauthorised access;

h) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose;

i) at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.

Ref: *IBTS/QA/POL/0002*
Ref: *IBTS/QA/SOP/0143*
Ref: *IBTS/RCI/SOP/0078*

8.4 Control of Records

8.4.1 Creation of records

The laboratory establishes and retains legible records.

Records are created at the time each activity that affects the quality of an examination is performed.

Ref: *IBTS/QA/POL/0002:*
Ref: *IBTS/DP/POL/0018*
Ref: *IBTS/RCI/SOP/0088*

8.4.2 Amendment of records

The laboratory ensures that amendments to records can be traced to previous versions or to original observations. Both the original and amended data and files are kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations.

Ref: *IBTS/QA/POL/0002*
Ref: IBTS/RCI/SOP/0002

8.4.3 Retention of records

a) The laboratory has the necessary procedures for identification, storage, protection from unauthorised access and changes, back-up, archive, retrieval, retention time and disposal of its records.

b) Retention times for records is specified.

c) Reported exam results are retrievable for as long as necessary.

d) All records are accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review.

Ref: *IBTS/DP/POL/0002*
Ref: *IBTS/DP/POL/0018*

Ref: *IBTS/RCI/SOP/0050:*
Ref: *IBTS/DP/SOP/0006:*
Ref: *IBTS/RCI/SOP/0088*

8.5 Actions to address risks and opportunities

8.5.1 Identification of risks and opportunities for improvement

The laboratory identifies risks and opportunities for improvement associated with the laboratory activities to:

a) prevent or reduce undesired impacts and potential failures in the laboratory activities;

b) achieve improvement, by acting on opportunities;

c) assure that the management system achieves its intended results;

d) mitigate risks to patient care;

e) help achieve the purpose and objectives of the laboratory.

Ref: *IBTS/RCI/SOP/0080*
Ref: *IBTS/QA/QM/0001*
Ref: *IBTS/RR/POL/0002*

8.5.2 Acting on risks and opportunities for improvement

The laboratory prioritises and acts on identified risks. Actions taken to address risks are proportional to the potential impact on laboratory examination results, as well as patient and personnel safety.

Ref: *IBTS/RCI/SOP/0080*
Ref: *IBTS/RCI/SOP/0066*

8.6 Improvement

8.6.1 Continual improvement

a) The laboratory continually improves the effectiveness of the management system including pre-examination, examination and post examination

processes as stated in objectives and policies and objectives. This is performed and documented through;

- Change Control (*IBTS/QA/SOP/0006*)
- Periodic Document Review *(IBTS/QA/POL/0002)*
- Equipment Maintenance (*IBTS/QA/VMP/0006)*
- Monitoring of Turnaround 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 (See HR policy ref: IBTS Policies and Procedures/Section 5/5.6 Performance Development System)
- 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, IBTS/RCI/SOP/0080 IBTS/RCI/RL/0001_1, IBTS/RCI/RL/0001_2)
- Laboratory meetings (IBTS/RCI/SOP/0066)

b) The laboratory identifies and selects opportunities for improvement and develops, documents, and implements any necessary actions. Improvement activities are directed at areas of highest priority based on risk assessments and the opportunities identified.

c) The laboratory evaluates the effectiveness of the actions taken.

d) Laboratory management ensures that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.

e) Laboratory management communicates its improvement plans and related goals to personnel through regular staff meetings.

Ref: *IBTS/RCI/SOP/0080*
Ref: *IBTS/RCI/SOP/0066*

8.6.2 Laboratory patient, user & personnel feedback

The RCI Laboratory seeks feedback from its patients, users and personnel. Feedback is analysed and used to improve the management system, laboratory activities and services to users.

Records of feedback are maintained including actions taken. Communication is provided to personnel on actions taken arising from their feedback.

Ref: *IBTS/RCI/SOP/0066*

8.7 Nonconformities and corrective action

8.7.1 Actions when nonconformity occurs

When a nonconformity occurs, the laboratory;

a) Responds to the nonconformity and, as applicable:

   1) Takes immediate action to control and correct the nonconformity.

   2) Address the consequences, with a particular focus on patient safety including escalation to the appropriate person.

b) Determine the cause(s) of the nonconformity.

c) Evaluate the need for corrective action to eliminate the cause(s) of the non-conformity , in order to reduce the likelihood of recurrence or occurrence elsewhere, by:
   1) Reviewing and analysing the nonconformity;

   2) Determining whether similar nonconformities exist, or could potentially occur;

   3) Assess the potential risk(s) and effects if the nonconformity recurs

d) Implement any action needed.

e) Review and evaluate the effectiveness of any corrective action taken.

f) Update risks and opportunities for improvement, as needed.

g) Make changes to the management system, if necessary.

Ref: *IBTS/QA/SOP/0068*

8.7.2 Corrective action effectiveness

Corrective actions implemented are appropriate to the effects of the nonconformities encountered and will mitigate the identified cause(s).

8.7.3 Records of nonconformities and corrective actions

The laboratory retains records as evidence of the

a) nature of the nonconformities, cause(s) and any subsequent actions taken, and

b) evaluation of the effectiveness of any corrective actions.

Ref: *IBTS/QA/SOP/0068*

8.8 Evaluations

8.8.1 General

The laboratory conducts evaluations at planned intervals to demonstrate that the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document.

Ref: *IBTS/RCI/SOP/0066*

8.8.2 Quality indicators

The process for monitoring quality indicators is planned and includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring. The indicators are periodically reviewed to ensure continued appropriateness.

Ref: *IBTS/RCI/SOP/0076*
Ref: *IBTS/RCI/SOP/0066*

8.8.3 Internal audit

8.8.3.1 The laboratory conducts internal audits at planned intervals to provide information on whether the management system

a) conforms to the laboratory's own requirements for its management system, including the laboratory activities,

b) is effectively implemented and maintained.

Ref: *IBTS/QA/POL/0006*
Ref: *IBTS/QA/SOP/0076*

Ref: *IBTS/RCI/SOP/0070*

8.8.3.2 The laboratory plans, establishes, implements and maintains an internal audit programme that includes:

a) priority given to risk to patients from laboratory activities;

b) a schedule which takes into consideration identified risks, the outcomes of both external evaluations and previous internal audits, the occurrence of nonconformities, incidents and complaints; and changes affecting the laboratory activities;

c) specified audit objectives, criteria and scope for each audit;

d) selection of auditors who are trained, qualified and authorised to assess the performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited;

e) ensuring objectivity and impartiality of the audit process;

f) ensuring that the result of the audits are reported to relevant personnel;

g) implementation of appropriate correction and corrective actions without undue delay;

h) retention of records as evidence of the implementation of the audit programme and audit results.

Ref: *IBTS/QA/POL/0006*
Ref: *IBTS/QA/SOP/0076*
Ref: *IBTS/RCI/SOP/0070*

8.9 Management Review

8.9.1 General

Laboratory management review its management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness, including the stated policies and objectives.

Ref: *IBTS/RCI/SOP/0066*

8.9.2 Review Input

The inputs to management review are recorded and include evaluations of at least the following:

a) status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources;

b) fulfilment of objectives and suitability of policies and procedures;

c) outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies;

d) patient, user and personnel feedback and complaints;

e) quality assurance of result validity;

f) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;

g) performance of external providers;

h) results of participation in interlaboratory comparison programmes;

i) other relevant factors, such as monitoring activities and training.

Ref: *IBTS/RCI/SOP/0066*

8.9.3 Review Output

The outputs from the management review are a record of decisions and actions related to at least:

a) The effectiveness of the management system and its processes;

b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;

c) Provision of required resources;

d) improvement of services to patients and users;

e) any need for change.

Laboratory management ensures that actions arising from management review are completed within a specified time frame.

Conclusions and actions arising from management reviews are communicated to laboratory personnel.

Ref: *IBTS/RCI/SOP/0066*

9. OTHER LABORATORY REQUIREMENTS

9.1 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.*

9.2 Blood Component Storage

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

9.3 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*.

Note: The following sections describe Traceability and Haemovigilance where IBTS RCI laboratory acts as a HBB.

10. TRACEABILITY REQUIREMENTS

10.1 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.

10.2 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).

10.3 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'.

10.4 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.

10.5 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.

10.6 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.*

10.7 The RCI laboratory utilises a 'Bag & Tag' traceability system. The Bag & Tag Label BT - 0396 is attached using a plastic tie onto all blood / blood components.

10.8 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.

10.9 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

10.10 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.

10.11 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.

10.12 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.

10.13 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.

11 HAEMOVIGILANCE REQUIREMENTS

11.1 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.

11.1.1 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.

11.1.2 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.

11.1.3 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: 2022. Refer to Haemovigilance handbook, *BT - 0566*.

11.2 Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs)

11.2.1 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.

11.2.2 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.*

11.2.3 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.*

11.2.4 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".

11.2.5 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.

11.2.6 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.

11.2.7 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.

11.2.8 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*.

11.2.9 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.

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

11.2.11 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.

11.2.12 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.

11.2.13 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.*

11.2.14 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.

11.2.15 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.

11.2.16 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.

11.2.17 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.

11.2.18 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.

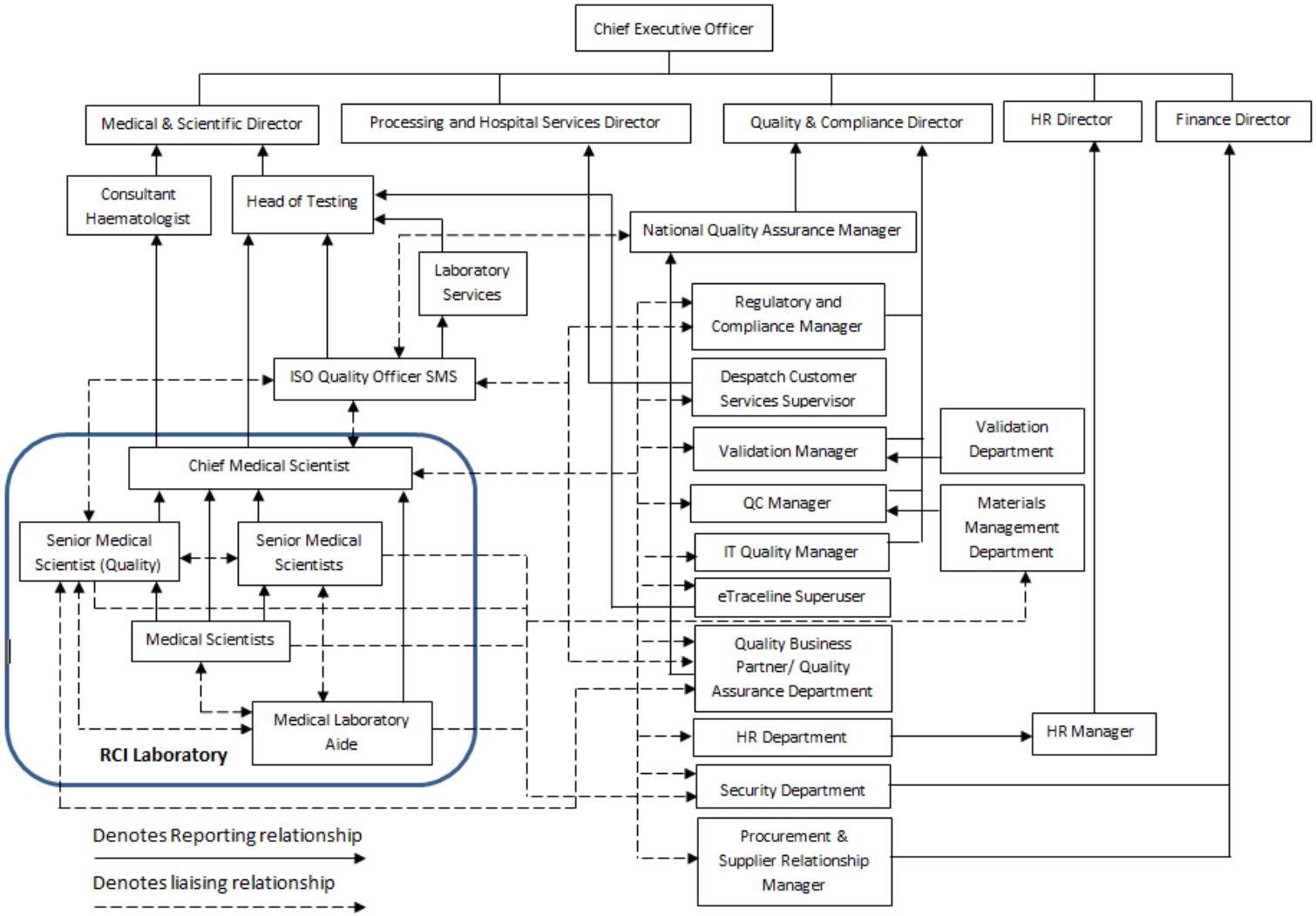
11.3 Medicinal Products

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*.

12 ATTACHMENTS

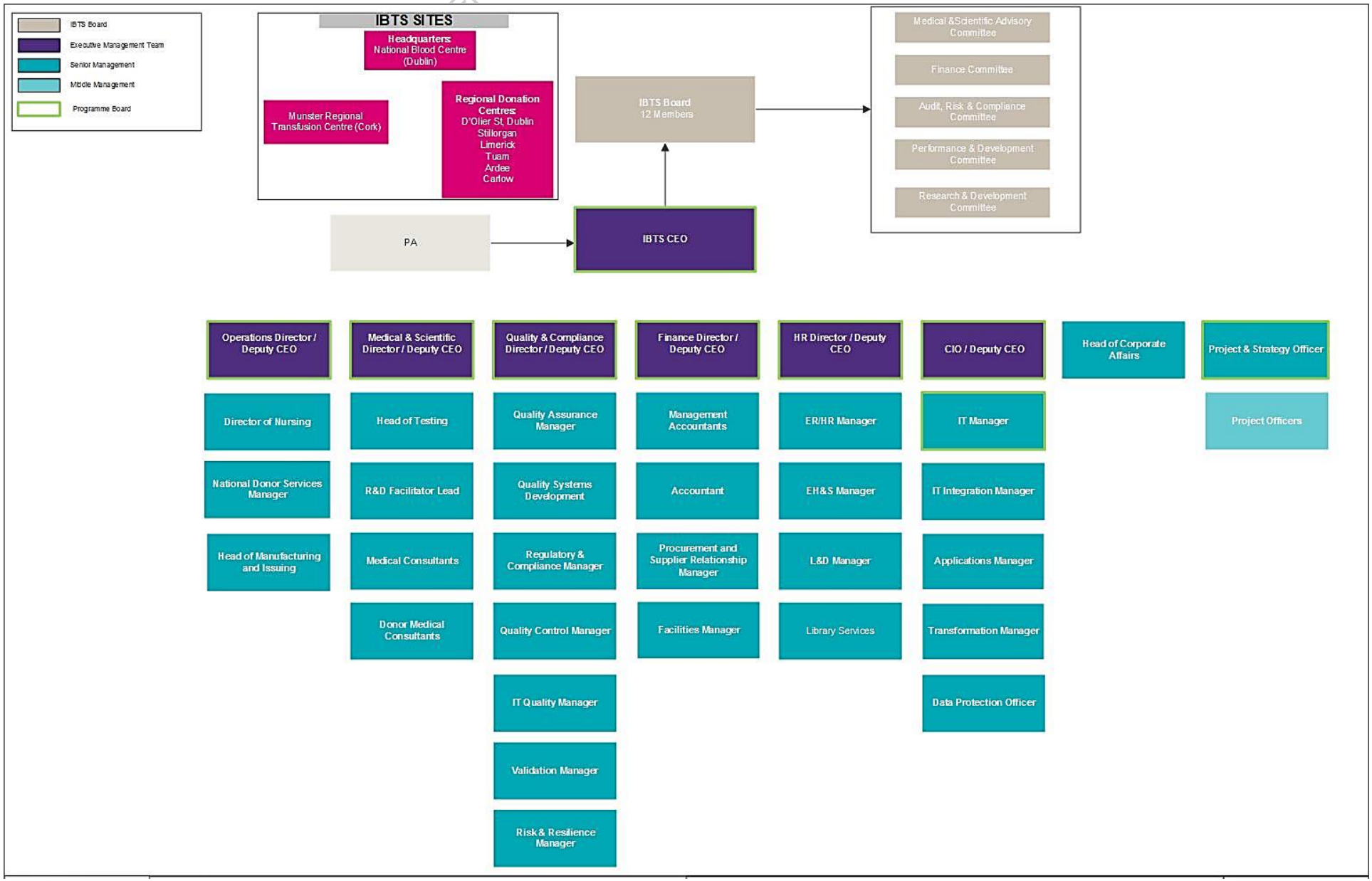
12.1 RCI Organisation Chart
12.2 IBTS Management Organisational Chart
12.3 RCI Process Flow
12.4 RCI and QMS interactions Process Flow

RCI Organisation Chart

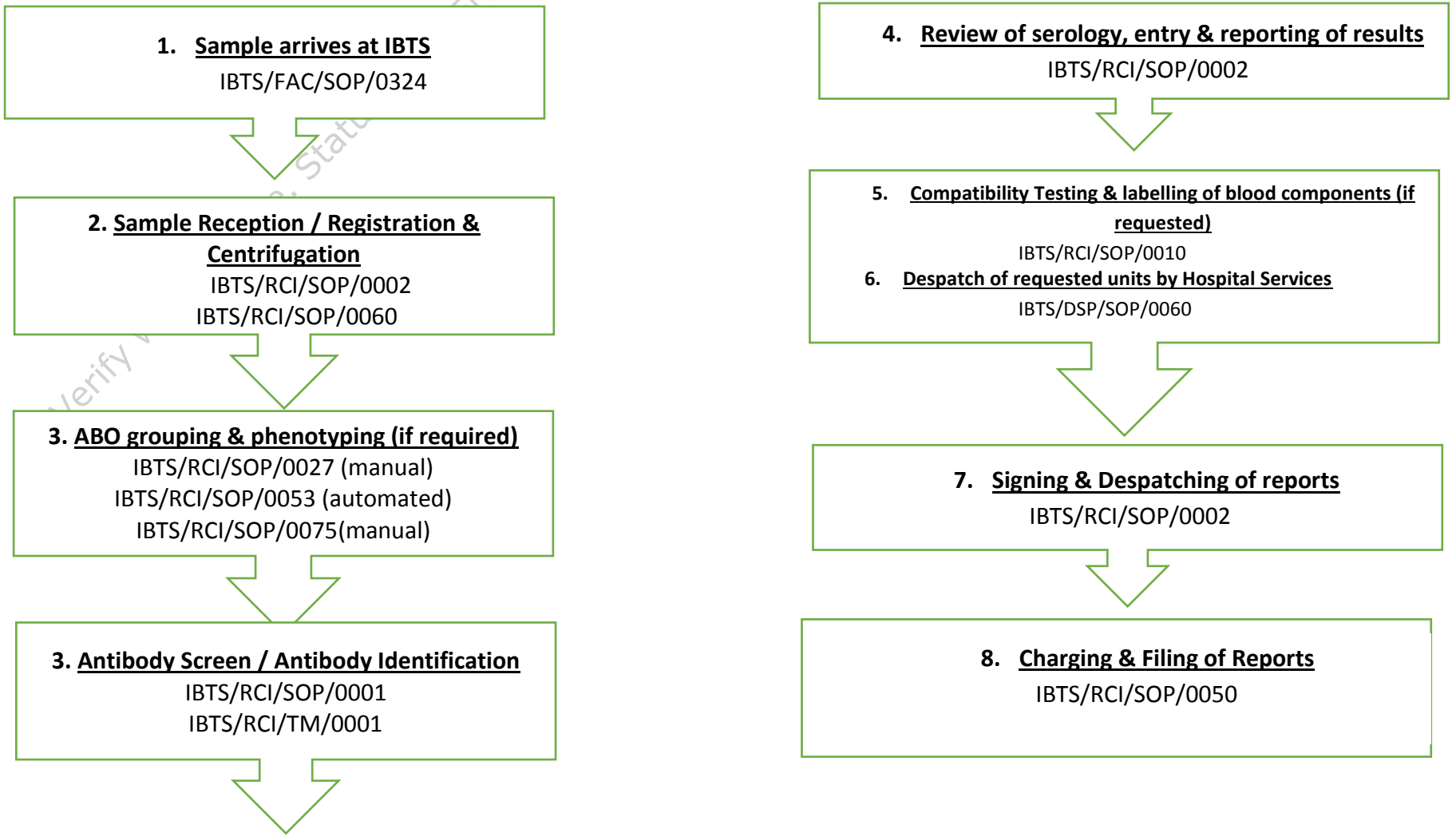


Denotes Departments that RCI outsource activities to that have a direct impact on patient testing as per IBTS/RCI/POL/0004

RCI Management Organisational Chart



RCI Process Flow



RCI and QMS Interactions Process Flow