



TITLE: QUALITY MANUAL (PATHOLOGY DEPARTMENT)

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Change Description:

- Section 4.1.2 Fig. 1 "Andrology" deleted, Phlebotomy Saturday service included and frequency of POC meetings defined as six months.
- Section 4.3.1 reference to masterlist of documents in procedure BSC/QA/SOP/009 changed to section 1.4.
- Section 4.13.3 reference to RCPATH guidelines document changed to current version.
- Section 4.15.1 "Diabetes Nurse Specialist" added as an attendee to the annual Management Review meeting and amended to define frequency of POC meetings as six months.
- Section 5.3.4 LAMS (Laboratory Asset Management System) changed to HAMS (Hospital Asset Management System).

Reason for Change:

- To close non conformances QA/016/11 and PATH/006/11.



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6.2 Titled “The Quality Policy of the Pathology Department”	
6.3 Titled “Laboratory Information System (L.I.S.) Sunquest (Misys) Current Version”	



1.0 INTRODUCTION TO QUALITY MANUAL

The purpose of this document is to define in clear terms, the policies, practices and procedures that control the effective delivery of the services provided as it relates to the Pathology Department, point of care testing activity and Haemovigilance and blood component traceability activities at the Bon Secours Hospital, College Road, Cork.

1.1 This document forms the organisation's response/ approach to the requirements of the following regulations and standards:-

- The current version of the International Standard ISO 15189 titled "Medical Laboratories Particular Requirements for Quality and Competency".
- The current version of the International Standard ISO 22870 titled "Point of Care Testing (POCT) – Requirements for Quality and Competence".
- EU Directive 2002/98/EC titled "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.
- EU Directive 2004/33/EC Annex IV titled "Storage, Transport and Distribution Conditions for Blood and Blood Components".
- Statutory instruments 360 of 2005, 562 and 547 of 2006 which adapt the EU Directives as defined above into Irish law.
- AML-BB current version titled "Minimum Requirements for Blood Transfusion Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC".
- INAB terms and conditions (current version)

These documents as defined above are listed in "the masterlist of documents of external origin" which is located in the shared area/Pathology/Quality/Masterlist of Documents. Therefore, this manual incorporates within the ISO 15189 framework our top level response to meeting the minimum requirements as laid out in the AML-BB document as defined above.

1.2 Our Quality Management System is based on the understanding that each individual is responsible for the Quality of their contribution and that each Supervisor and Head of Department has a responsibility to ensure that this policy is understood and followed at all times.

1.3 In the event of conflict between this document and specific contracted requirements, then the latter takes precedence.

2.0 REFERENCE DOCUMENTS

2.1 ISO Guide 31 titled "Quantities and Units".

2.2 As per documents defined in section 1.1 above, which are listed in "the masterlist of documents of external origin" which is located in the shared area/Pathology/Quality/Masterlist of Documents.



2.3 Current master lists of controlled documentation are maintained electronically. These master lists constitute the Pathology divisions, Departmental Standard Operating Procedures, Policies, Guidelines and including relevant and traceable standards, specifications and forms.

3.0 TERMS AND DEFINITIONS

3.1 The terms and definitions used in this document are the terms and definitions that are commonly understood (with a single interpretation) by our users i.e. Internal and External customers and by Laboratory staff.

3.2 For the purpose of international standard “**ISO 15189**” the term Laboratory Director refers to the Clinical Director and the Laboratory Services Manager. One of the five Medical Consultants is appointed as Clinical Director on a rotational basis. Clinical issues of the individual laboratories are directed by the following Medical Consultants:-

- Consultant Pathologists.
- Consultant Microbiologist.
- Consultant Chemical Pathologist.

3.3 Point of Care Testing (Near Patient Testing)

Testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient.

4.0 MANAGEMENT REQUIREMENTS

4.1 ORGANISATION AND MANAGEMENT

4.1.1 Organisational details

The legal entity is the Bon Secours Health System Ltd.

1. Full name and address - The Bon Secours Health System Ltd.,
Division of Pathology, College Road, Cork.
2. Telephone – 021-4542005.
3. Fax – 021-4341983.
4. E.Mail:- sobrien@bonsecours.ie.
5. Number of staff employed – approximately 78 personnel.

4.1.2 Provision of Services

a. Hospital

- The Bon Secours Hospital Cork is one of the largest independent private Hospitals in Europe with 343 beds, catering for over 18,000 admissions and 29,000 outpatient attendances each year.
- The Hospital encompasses the following main activities:-
Angiography, Dietetics, Cardiology, Health Screening, Respiratory Medicine, Theatre, Diagnostic Imaging, Endoscopy, Intensive Care Unit, Out Patient Department, Pathology and Physiotherapy.
- The following specialities are provided:-
Paediatrics, Psychiatry, Urology, Ophthalmology, Rheumatology, Densitometry, Plastic Surgery and Gynaecology, Oral Surgery, Orthopaedic, ENT Surgery, Oncology and Dermatology.



- A Point Of Care Committee is in place to manage and control near patient testing, refer to fig. 1 below.
- The Hospital does not provide an Accident and Emergency service.

b. Pathology

- Below in figure 1 is a listing and description of services provided by the Pathology department. The services described here under are designed so that the needs and expectations of clinical personnel and patients are satisfied.

Fig. 1

SERVICE NAME	SERVICE DESCRIPTION
Provision of Diagnostic Service	There is a wide range of Pathology tests available. For the full list of diagnostic services refer to document BSC/PATH/GDE/001 titled “Primary Sample Collection Manual”.
Biochemistry	The automated chemistry section provides analysis of samples for renal, liver, cardiac, lipid, iron studies and specific protein assays. The Immunology section performs Electrophoresis, allergy and associated assays while the Immunoassay section performs endocrine, tumour marker, troponin and therapeutic drug monitoring (TDM) assays.
Haematology	A diagnostic haematology service is provided which includes blood counts and blood film examination. Routine coagulation screening includes PT-INR, APTT and Fibrinogen tests.
Blood Transfusion	The Hospital Blood Bank provides routine and emergency compatibility testing for both surgical and medical patients. The Blood Bank Laboratory provides a stock of manufactured blood products including solvent detergent plasma and albumin.
Histopathology	The Histopathology department provides a varied range of services including Tissue Pathology (including frozen sections for rapid diagnosis), Non-Gynaecological Cytology and Immunology .
Microbiology	The Laboratory examines a diverse range of specimens for bacterial, fungal, viral and parasitic infections and determines the sensitivity of bacteria to antibiotics. The department provides a clinical service which ensures that patients are treated in a timely and effective manner. The department works closely with the Hospital Infection Prevention and Control Department.
Related Diagnostic Services	Sweat test, Glucose tolerance test and Mantoux testing.
Phlebotomy Service	The Phlebotomy department on a routine basis 7.00am - 4.30pm Monday to Friday and Saturday from 7.00am - 11.00am take blood samples for diagnostic testing from in-patients. Outside these hours, blood samples are taken by trained Hospital personnel. Outpatient Phlebotomy is from 8.00am – 12.30pm and 2.00pm to 4.30pm Monday to Friday.



SERVICE NAME	SERVICE DESCRIPTION
Consultant Service	Consultant Pathology Services are available in the following specialities, Histopathology, Immunology, Clinical Microbiology, Haematology, Blood Transfusion and Biochemistry.
Warfarin Clinic	An outpatient Warfarin clinic service is available on Tuesdays and Thursdays between 8.30 am and 12.00 noon.
Therapeutic Phlebotomy	The therapeutic phlebotomy procedure is available for the treatment of certain clinical conditions such as haemochromatosis and polycythaemia. This process is performed by Phlebotomy staff under clinical guidance.
Executive Health Screening	To meet customer requirements a full range of pathology test packages are available as part of health screening. These packages are designed to cover any combination of pathology tests as required by the customer.
Haemovigilance Service	<p>All Haemovigilance events are documented and reported to the National Haemovigilance Office as per the requirements of the Hospital Transfusion Handbook, reference BSC/HV/MAN/001. The Bon Secours Pathology Department is committed in conjunction with the Haemovigilance Nurses to providing a reporting mechanism that assists the Quality Management Review Process. The Hospital Transfusion committee is comprised of:-</p> <ul style="list-style-type: none"> • Consultant Pathologist responsible for Blood Transfusion • Chief Medical Scientist in Blood Transfusion • Senior Medical Scientist in Blood Transfusion • Haemovigilance Nurses • Regional Blood Transfusion Service Director • School of Nursing representative • Representative of major clinical users (e.g. Oncology, Orthopaedics, Theatre) • Head of Department, Phlebotomy • Pharmacy representative • Laboratory Quality Assurance Officer • Any others deemed appropriate by the committee <p>The Hospital Transfusion Committee meet at least quarterly with the agenda distributed at least one week in advance of the meeting.</p> <p>The agenda will include as standard the following items:-</p> <ul style="list-style-type: none"> • Minutes of previous meeting • Matters arising from minutes of previous meeting • Inventory management/ supplier review • Haemovigilance report • Irish Blood Transfusion Service report • Quality Systems report (Laboratory ISO15189 and Hospital Joint Commission International Accreditation) • Any other business <p>The minutes of the Hospital Transfusion Committee meeting are circulated to the Hospital Manager in addition to the committee members.</p> <p>The Hospital Transfusion Committee is detailed by procedure BSC/HV/SOP/003.</p>



SERVICE NAME	SERVICE DESCRIPTION
Point of Care Testing Service	<p>A point of care (POC) testing service is in place that meets clinical requirements as defined by the POC Committee. The POC Committee reports to Hospital/ Laboratory Management for point of care testing services/ issues. The terms of reference of the POC Committee are:-</p> <ul style="list-style-type: none"> • Advice on policy regarding the performance of near patient tests in a clinical setting. • Advice on the placement of specific testing devices, including analytical instruments and reagents systems in clinical areas. • To recommend user training and certification programmes for systems used in clinical areas. • To recommend QC programmes (internal and external) in clinical areas. <p>This POC Committee meets every 6 months and if clinically required. The POC meetings are chaired by the Consultant Chemical Pathologist and the committee consists of:-</p> <ul style="list-style-type: none"> • Chief Medical Scientist, Biochemistry • Nursing Practice Development Officer • Clinical Services Manager • Validation Technician • Diabetes Nurse Specialist • Haemovigilance Nurse CNM2 • Other attendees as invited by the chair person. <p>Minutes of the meeting are recorded and circulated.</p>

Note: The current version of the Primary Sample Collection Manual BSC/PATH/GDE/001 (sections 4.1, 4.2 and 4.3) defines the request forms to be used, how to complete the request form and how to label the specimen container for tests traceable to the services listed above.

- The scope of accreditation to “**ISO 15189**” is controlled by the Irish National Accreditation Board (INAB) and displayed on their website www.inab.ie.

4.1.3 The Laboratory is committed to performing its activities in accordance with the requirements of international standards “**ISO 15189**” and **ISO 22870** (current versions). All work relevant to the scope of “**ISO 15189**” is carried out in the permanent facility defined in the organisational details, reference 4.1.1. Refer to attachment 7.1 titled “**Pathology Department Layout**” of procedure BSC/PATH/SOP/040. The Laboratory was first accredited by the Irish National Accreditation Board on the 6th September 2004 as being in compliance with the International Standard ISO/IEC/15189. The scope of the accreditation is as detailed in Registration No. 153MT.

4.1.4 Lines of Communication and Responsibility:

- Responsibility of personnel in the Laboratory is defined by formal job descriptions. Job descriptions are in place for each position. The approved responsibilities and the contract of employment associated with each position are to identify, manage and prevent a conflict of interest.



- Furthermore, the lines of communication and responsibility are clearly defined in the attachment 6.1 of this document titled “**Organisational Charts (Pathology/ Blood Transfusion Departments/ Point of Care Testing)**”. All personnel must follow these lines of communication and authority without exception. The “**Corporate Compliance Plan: Code of Conduct**” document no. BP0030 (current version) ensures that neither financial, political or conflict of interest considerations influence testing.

4.1.5 Laboratory Management and the Quality Management System.

- 4.1.5.1** - The Laboratory Management team consists of :-
- The Laboratory Services Manager.
 - Clinical Director.
 - Medical Consultants.
 - Consultant Histopathologists x 3 (full time and one of which has clinical Laboratory responsibility for Haematology and Blood Transfusion)
 - Consultant Microbiologist (full time)
 - Consultant Chemical Pathologist (part time)
 - Heads of Department consisting of:-
 - the Chief Scientists in Histopathology, Blood Transfusion/ Haematology, Microbiology and Biochemistry.
 - Head of Department in Specimen Reception, Phlebotomy and Pathology Office.
 - Laboratory Information System Manager.
 - Laboratory Quality Assurance Officer.
 - Haemovigilance Nurse.
 - Diabetes Nurse Specialist

The above constitute the Laboratory Quality Management Review team.

- Laboratory Management led by the Laboratory Services Manager ensures the following:-
 - a) That Laboratory personnel have the necessary authority and resources to carry out their duties as reflected in their job description. Job descriptions are in place for each position. The necessary resource requirements are identified in the annual training plan and capital and human resource budgetary submissions made by the Laboratory Services Manager.
 - b) That personnel are free from any undue internal or external commercial, financial or other pressures and influences that may adversely affect the quality of their work. Refer to the following hospital policies:-
 - **Disciplinary Procedure** document number HR0005
 - **Policy to Promote Dignity and Respect at Work** (Policy on Bullying/ Harassment, Sexual Harassment) document number HR0004
 - **Patient and Family Grievance Procedure** document number BP0009
 - **Corporate Compliance Plan: Code of Conduct** document number BP0030
 - **Gratuity Policy** document number BP0010



- c) That the hospital policies reference document titled “**Patient Privacy and Confidentiality Policy**” document number BP0033 with regard to patient confidentiality is strictly adhered to. Each employee is contractually bound to refrain from divulging any patient information. Any breaches of this policy will be fully investigated and appropriate censure will be taken as per the hospital “**Disciplinary Procedure**”.
- d) That the Laboratory are not involved in any activity that would diminish confidence in its competence, impartiality, judgement, or operational integrity. Reference “**Corporate Compliance Plan: Code of Conduct**” document number BP0030.
- e) That the organisational and management structures of the Pathology department are clearly defined. Refer to attachment 6.1 of this document titled “**Organisational Charts (Pathology/ Blood Transfusion Departments/ Point of Care Testing)**”. The **organisational chart** defining the Management structure of the Laboratory is fundamental to ensuring the Quality Management System is adequate in design, implementation, maintenance and continuous improvement.
- f) That the responsibilities, authority and inter-relationships of personnel are defined in clear terms in job descriptions. An authorised job description is available for each position within the Laboratory including Haemovigilance Nurses and Diabetes Nurse Specialists. Each job description is approved by the Laboratory Services Manager/ Director of Nursing and where relevant in consultation with the relevant Medical Consultant (Laboratory). Dr. O'Murchu, Consultant Pathologist has overall responsibility and authority for Haemovigilance/ Traceability activities as it applies to meeting the regulatory requirements specified in Articles 14 and 15 of EU Directive 2002/98/EC. In addition, Munster Regional Transfusion Centre clinical personnel provide a Consultant/ Advisory service. On signing the contract of employment, personnel are accepting the job description for that position. The control of job descriptions is defined by procedure BSC/QA/SOP/010 titled “**Control of Training in the Pathology Laboratory, Bon Secours Hospital**”.
- g) That adequately trained staff perform procedures that have an impact on the quality of service supplied. Procedural training is controlled by procedure BSC/QA/SOP/012 titled “**Control of Pathology Procedural Training Including Laboratory Induction of New Staff**” and the proficiency of scientific staff is controlled by BSC/QA/SOP/018 titled “**Pathology Proficiency Testing of Laboratory Staff to Ensure Competency**”.
- h) - That Scientific Management (the relevant Medical Laboratory Consultant and Chief Medical Scientist) have overall responsibility for providing the testing services including test interpretative services as appropriate as per section 4.1.2 of this document.
- The Clinical Director and fellow Laboratory Medical Consultants are responsible for:-
- directing clinical issues.
 - communicating directly with the Heads of Department in the clinical Laboratories.
 - providing advice on the choice of tests.
 - providing advice on the use of Laboratory services.
 - interpretation of Laboratory data.



- directing Haemovigilance and traceability as it applies to blood components (Dr. O'Murchu).
 - directing point of care testing (Prof. B. Buckley)
- The Laboratory Services Manager is responsible for providing the necessary resources (human, material, equipment) to meet the requirements of the provided services.
- i) That the Laboratory Quality Assurance Officer reporting to the Laboratory Services Manager has the necessary authority and responsibility for ensuring that the requirements of the Quality Management System ISO 15189/ ISO 22870 (current version) and EU Directive 2002/98/EC are implemented and adhered to. The Laboratory Quality Assurance Officer ensures that **defined review processes** for Quality Management Review are continuous and planned and that such reviews are conscious of the impact organisational change has on customer requirements.
- j) That deputies are in place for key functions. Refer to figure 2.

Figure 2

Key Function/ Activity	Position	Deputy
Laboratory Administration	Laboratory Services Manager	Chief Medical Scientist/ Laboratory QA Officer
Clinical Laboratory	Clinical Director	Consultant Pathologist(s)
Biochemistry (Clinical)	Consultant Chemical Pathologist	Consultant Pathologist (Dr. O'Murchu)
Biochemistry (Scientific)	Chief Medical Scientist	Senior Biochemist
Blood Transfusion/ Haematology (Clinical)	Consultant Pathologist (Dr. O'Murchu)	Consultant Microbiologist
Blood Transfusion/ Haematology (Scientific)	Chief Medical Scientist	Senior Medical Scientist
Pont of Care Testing (Clinical)	Consultant Chemical Pathologist	Consultant Pathologist (Dr. O'Murchu)
Haemovigilance	Haemovigilance Nurse CMN II	Haemovigilance Nurse CMN II
Histopathology (Clinical)	Consultant Pathologist	Any of the other 2 Consultant Pathologists
Histopathology (Scientific)	Chief Medical Scientist	Senior Medical Scientist
Microbiology (Clinical)	Consultant Microbiologist	Consultant Pathologist (Dr. O'Murchu)
Microbiology (Scientific)	Chief Medical Scientist	Senior Medical Scientist
Laboratory Information Systems	Laboratory Information System Manager	Sean O'Driscoll (Biochemistry Dept.)
Quality Assurance	Laboratory Quality Assurance Officer	Laboratory Services Manager
Specimen Reception	Head of Specimen Reception	Deputy Head of Specimen Reception
Phlebotomy	Senior Phlebotomist	Not Applicable
Pathology Office	Head of Pathology Office	Grade IV Clerical Officer



- 4.1.6** a. Laboratory Management have robust communication processes (refer to section 5.2.8) established within the Laboratory including:-
- Change Control System, reference BSC/QA/SOP/054.
 - Electronic issue of internal audit reports, reference BSC/QA/SOP/030.
 - Agenda and minutes for Head of Department meetings are circulated electronically, reference BSC/QA/SOP/020.
 - Agenda and minutes for the Monthly Quality Assurance meetings are circulated electronically, reference BSC/QA/SOP/020.
 - Agenda, reports and minutes of the Annual Management Review meetings are circulated electronically, reference BSC/QA/SOP/020.
 - Agenda, reports and minutes traceable to the Hospital Transfusion Committee meetings, reference BSC/HV/SOP/003.
 - Agenda and minutes of meetings traceable to defined structures set up between and including Hospital Manager, Laboratory Medical Consultants, Laboratory Services Manager and Heads of Department. These defined structures include;-
Quarterly Meetings attended by Hospital Manager, Laboratory Services Manager and Clinical Director.
Quarterly Clinical Management Meeting attended by Laboratory Consultants, Laboratory Services Manager, Quality Assurance Officer and Chief Medical Scientists and other personnel as required.
 - Quarterly point of care meetings, refer to fig. 1 in section 4.1.2.
 - Agenda, reports and minutes of the Laboratory Users Group are circulated electronically.
 - Logs of monthly reports of specimen/ form issues are circulated electronically to the Nursing Practice Development Office for review and circulation to Clinical Nurse Managers.
- b. The Quality Assurance Office, issues on a monthly basis updated logs of Customer Complaints, Non Conformances and Change Controls. The purpose of this communication is to:-
- Identify outstanding issues and agreed timelines.
 - Use this communication as a mechanism whereby the Head of Department verifies the effectiveness of the Quality Management System.
 - Use this communication to inform staff of key quality events at the regular departmental meetings.
- c. The Quality Notice Board located in the main corridor of the Laboratory, is posted with the minutes of the Monthly Quality Assurance meeting and the minutes and key reports traceable to the Annual Management Review meeting. These minutes are also posted electronically in the shared area in the file path
\\corkfp1\Shared\Pathology\Monthly Quality Assurance Meeting - Minutes.



4.2 QUALITY MANAGEMENT SYSTEM

4.2.1 The Laboratory Quality Management System is defined in its totality by the procedures it operates to control processes which meet the defined policies and are compatible with the ethos of the Bon Secours Health Care System. Laboratory Management ensure that all relevant personnel understand the documented policies, processes and procedures. The Quality Management system is defined by the master list of documents which is electronically retained and includes the Haemovigilance/ Traceability and point of care testing activities. The processes are defined by document BSC/QA/SOP/022 titled “**Functional Process Flow Charts**”. These process flow documents are the key building blocks on which our Quality Management System rests as these documents identify critical control points in each process.

4.2.2 Key Quality Management Elements

- Key quality management system elements are defined by the Quality Assurance process flow reference attachment 7.9 of BSC/QA/SOP/022 titled “**Functional Process Flow Chart**”.
- Key elements of the quality management system include:-

Procedure Controlling Key Element	Key Element
BSC/QA/SOP/010	Control of Training in the Pathology Laboratory, Bon Secours Hospital.
BSC/QA/SOP/020	Procedure for Quality Management Review
BSC/QA/SOP/024	Performance and Review of Internal Quality Control and External Quality Assessment Samples
BSC/QA/SOP/026	Control of Service System Non Conformance
BSC/QA/SOP/028	Complaints Handling System
BSC/QA/SOP/030	Internal Quality Audit Procedure
BSC/QA/SOP/040	Procedure for the Control of Pathology Equipment Including Service Contracts
BSC/QA/SOP/054	Procedure for the Control of Change to Equipment, Processes, Techniques and Controlled Documentation
BSC/HV/MAN/001	Hospital Transfusion Handbook

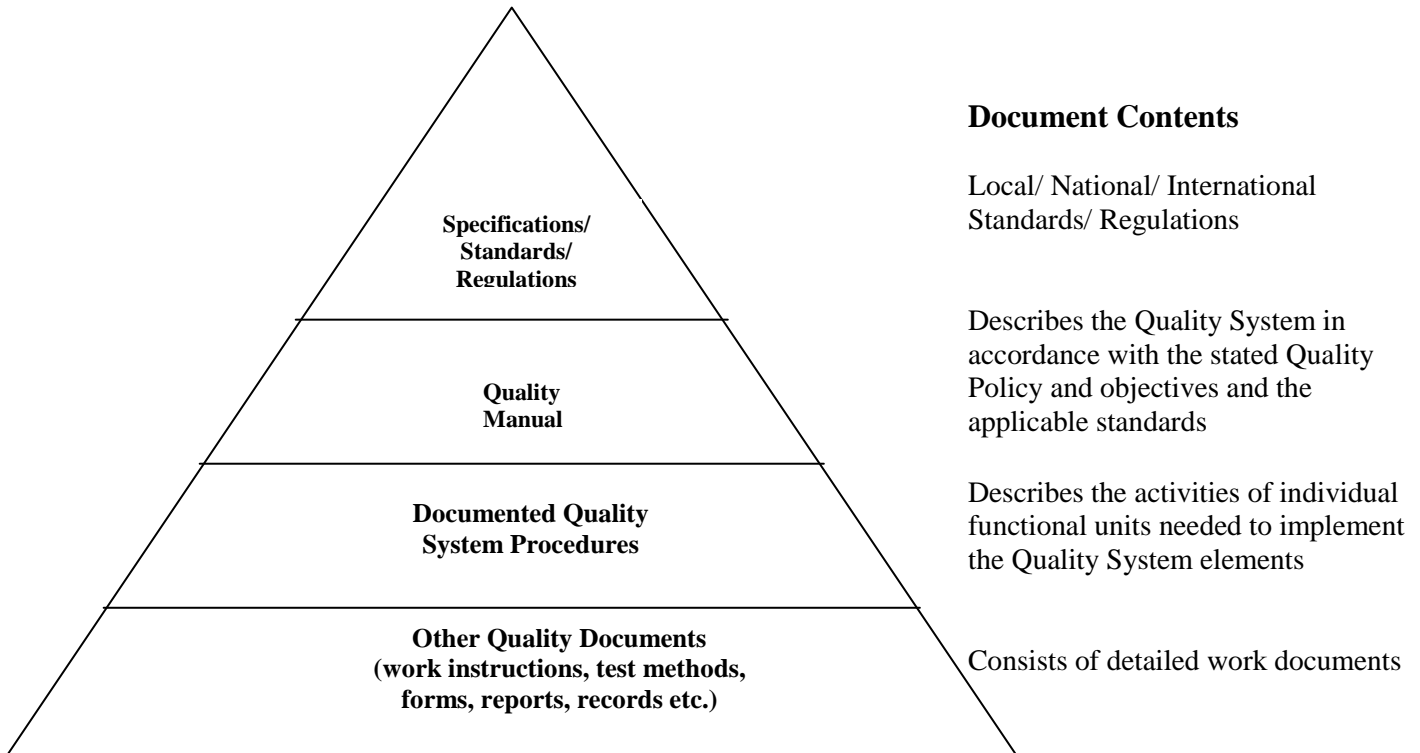
4.2.3 Policies and objectives of the Quality Management System

- The Pathology department quality policies and objectives are clearly defined in the quality policy statement. Refer to attachment 6.2 of this document titled “**The Quality Policy of the Pathology Department, Bon Secours Hospital Cork**”. The quality policy is approved by the Laboratory Director (Laboratory Services Manager/ Clinical Director) and the Hospital Manager. The policy is framed and wall mounted in the following locations:-
 - Laboratory Outpatient Reception
 - Phlebotomy
 - The Laboratory Corridor
 - The Laboratory Services Manager office



- All Laboratory staff are trained and familiar with the Quality Policy Statement.
- The Quality Policy Statement includes:-
 - a) A reference to the scope of service provided.
 - b) A statement on the Laboratories standard of service.
 - c) The objectives of the quality system
 - d) A commitment to ensuring personnel are familiar with the organisations quality policies and objectives and implementing/ adhering to authorised procedures at all times.
 - e) The Laboratories commitment to good professional practice, the quality of its examinations and compliance with the Quality Management System.
 - f) The Laboratory Management’s commitment to comply with the “**International Standards ISO 15189, ISO 22870**” and **EU Directive 2002/98/EC**.

4.2.4 - This Quality Manual defines and describes the quality management system and the structure of the documentation used in the quality management system and includes policies and procedures controlling Haemovigilance and Traceability. The hierarchy of the documentation system is described below.



- The Quality Manual is revised by the Laboratory Quality Assurance Officer at predefined intervals or following an audit as controlled by procedure BSC/QA/SOP/005 titled “**Operation of a Controlled Document System**”.
- All personnel are instructed on the use and application of the Quality Manual and all referenced documentation and of the requirements of their implementation.
- The Quality Manual including attachments is circulated to:-
 - The Laboratory Quality Assurance Officer
 - The Laboratory Services Manager
 - External locations as requested



For internal users an **electronic version** of the manual is stored on the desktop under an icon titled **Public Documents/ Pathology Documents**. The document is stored in Adobe Acrobat format, which allows all computer users to read the document while preventing modification. Instructions on how to use the electronic version of the manual have been issued to users. It is the responsibility of Heads of Department to ensure that all staff are familiar with accessing the document. The manual is also accessible on the Bon Secours Website www.bonsecoursireland.org under Cork in the Pathology Section.

INAB as per the requirements of PS10 are issued with an uncontrolled copy of the Quality Manual 6 weeks in advance of a scheduled visit.

- 4.2.5** Fundamental to our Quality Management System is the Laboratory Management's commitment to ensuring procedures and programmes are in place which are regularly monitored and demonstrates **proper calibration and functions of instruments**, reagents and analytical systems. The calibration and maintenance programmes are controlled by procedures including BSC/QA/SOP/040 titled "**Procedure for the Control of Pathology Equipment Including Service Contracts**" and BSC/QA/SOP/042 titled "**Control of Inspection and Test Equipment**".

4.3 DOCUMENT CONTROL

- 4.3.1**
- Procedures BSC/QA/SOP/005 titled "**Operation of a Controlled Document System**" and BSC/QA/SOP/009 titled "**Procedure for the Control of Archive Documentation and Samples**" control all documents and information (from internal and external sources) that form part of the Laboratories quality documentation including Haemovigilance/ Traceability and point of care testing. A **document** may be in hardcopy or electronic format and may consist of any information or instruction including but not limited to the masterlist of documents as listed in section 1.4 of this document.
 - The Hospital Best Practice Department control Hospital policies and procedures using the Q-Pulse software application. These documents are accessed using the Hospital Intranet. Documents that are relevant and used by the Pathology department are listed in "the masterlist of documents of external origin" which is located in the shared area/Pathology/Quality/Masterlist of Documents.
 - Records are archived internally and externally as per the requirements of procedure BSC/QA/SOP/008 titled "Procedure for the Control of Archive Laboratory Documentation and Histopathology Material including Tissue Blocks and Slides".
 - A master list of documents is retained electronically using Microsoft Excel. This master list defines:-
 - Document Number
 - Document Title
 - Document Version
 - Effective Date
 - Next Review Date

The Document Controller is responsible for updating and maintaining this master list of document.



- Obsolete documents are retained for defined periods as per the requirements of BSC/QA/SOP/009 titled “**Procedure for the Control of Archive Documentation, Specimens and Preparations**”. The retention period for documents meet the minimum requirements of the Royal College of Pathologists as stated in document titled “**The Retention and Storage of Pathological Records and Archives**” (current version) and that of current applicable regulations e.g. 2002/98/EC.
- The records are maintained as:-
 - Hardcopy
 - Electronic on floppy disc/ CD or hard drive

The storage medium is defined for each record type in BSC/QA/SOP/009 titled “**Procedure for the Control of Archive Documentation, Specimens and Preparations**”.

- All changes to Laboratory equipment, processes or methods are authorised and are clearly identified on the cover page of the standard operating procedure under the heading change description.
- The issue revision and authorisation of Document Control procedures are the responsibility of the Laboratory Quality Assurance Officer.
- **Definition of Document**
Document is any information or instruction in softcopy or hardcopy that is included in the listing defined in section 6.3 of procedure BSC/QA/SOP/009 titled “**Procedure for the Control of Archive Documentation, Specimens and Preparations**”.

4.3.2 Procedures are in place to ensure:-

- a) All documents issued to Laboratory personnel as part of the Quality Management System are reviewed and approved by authorised personnel prior to issue. Refer to BSC/QA/SOP/005 titled “**Operation of a Controlled Document System**”.
- b) - A Circulation List and Document Review List identifying the current valid versions and their distribution are maintained.
 - Attachment 7.2 of procedure BSC/QA/SOP/005 controls the Document Review History where the 2 year review does not yield a revision or where the review identifies minor amendments pending revision of the document. These minor amendments are made by hand.
 - Attachment 7.2 “**Document Review History**” of procedure BSC/QA/SOP/005 titled “**Operation of a Controlled Document System**” controls the Document Review History (master record) of all reviews and amendments made to a document. The Document Review History is maintained with the current version of the document.
 - Attachment 7.3 “**Circulation List**” of BSC/QA/SOP/005 controls the circulation and withdrawal of procedure type documents. Obsolete Circulation Lists are maintained with the master obsolete document.
 - The circulation and review status for documents of **external origin** is controlled by the use of a document control stamp which is maintained in a secure location by the Document Controller.



- c) Only currently authorised versions of appropriate documents are available at the point of use as per the Circulation List or document control stamp in the case of documents of external origin. This is controlled by procedure BSC/QA/SOP/005 titled **“Operation of a Controlled Document System”**.
- d) Document types including standard operating procedures (as defined by attachment 7.1 of procedure BSC/QA/SOP/001) must be reviewed every 2 years for adequacy and revised as required. All revisions must be authorised prior to implementation, refer to BSC/QA/SOP/005 titled **“Operation of a Controlled Document System”**.
- e) Obsolete versions of documents are removed from the point of use normally when the revised version is being implemented. Obsolete copies of document types (as described in attachment 7.1 of BSC/QA/SOP/001) are disposed of. The disposal of such documents is documented on attachment 7.3 of procedure BSC/QA/SOP/005.
- f) Retained or archived superseded documents are stamped with a document control stamp called “Obsolete Document”. Obsolete superseded retained documents are retained in a location that is distinct and readily separated from the location of the current version of documents. Refer to BSC/QA/SOP/005 titled **“Operation of a Controlled Document System”**.
- g) The Laboratory allows for the amendment by hand of documents only where the change “is a small change for purpose of clarity of instruction” pending the re-issue of documents. The approval of the amendment is achieved by the Head of Department or Laboratory Quality Assurance Officer initialling and dating the hand written amendment(s). The Head of Department/ nominee must communicate by e-mail/ mailbox such changes and a copy of this change must be retained with the master document.

Refer to procedure:-

- BSC/QA/SOP/005 **“Operation of a Controlled Document System”**
 - BSC/QA/SOP/007 **“Completion and Retention of Quality Records”**
- h) - Changes to documents on the Laboratory Information System, Misys and CoPath (current versions) are controlled as follows:-

Type of Change	Control
Changes to maintenance or parameterisation files	BSC/QA/SOP/054 titled “Procedure for the Control of Change to Equipment, Processes, Techniques and Controlled Documentation”
Modification of data	<ul style="list-style-type: none"> - As per the appropriate Sunquest and CoPath User Manual - BSC/PATH/SOP/060 titled “Procedure for the Review and Release of Reports to Users” - BSC/PATH/SOP/030 titled “Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens” - BSC/IT/SOP0/020 titled “Operation and Use of the CoPathPlus Anatomical Pathology System (Current Version)”



- Changes to documents controlled by the Document Controller are controlled by secure access as per the requirements of BSC/IT/SOP/001 titled “**Laboratory Information System – User Requirements (Network and Applications)**”.

- i) The **horizontal audit program** controlled by procedure BSC/QA/SOP/030 titled “Internal Quality Audit Procedure” ensures that **quality documents** are audited **annually** (reviewed).

4.3.3

- Controlled documents relevant to the Quality Management System and under the control of internal Document Control are **uniquely** identified. This unique identification includes:-
 - clear document name or title.
 - document number including revision number and revision date
 - a page number
 - name of person who wrote document
 - name of reviewer(s) of document
 - name of authoriser(s) for document
 - a description of the major changes from one version of the document to the next
 - a clear description of the source of the document i.e. BSC meaning Bon Secours Cork.

Reference BSC/QA/SOP/001 titled “**Document Numbering System**”

- Controlled documents relevant to the Quality Management System and external in origin are uniquely identified. This unique identification includes:-
 - Date received (by Document Control)
 - Edition Number
 - Number of Pages
 - Authorised by and date
 A document control stamp is used for this purpose.

4.4 REVIEW OF CONTRACTS

4.4.1

- The contractual arrangement between the hospital wards/ internal locations i.e. outpatients, x-ray etc. and the Laboratory is defined by the Laboratory Request Form used to requisition the Laboratory services. The Laboratory services available are defined in the “Primary Sample Collection Manual” BSC/PATH/GDE/001 which has been issued to our internal/ external users of the Pathology services. Internal users view the document in the public documents folder and external users view the document on the Bon Secours web site www.bonsecoursireland.org.
- The contractual arrangement between customers external to the hospital location and the Laboratory is defined by the Laboratory Request Form used to requisition the Laboratory services.
- A master list of internal/ external customers is retained and maintained by the Laboratory Services Manager.



- The approved requisition forms (the contract) to be used by internal/ external customers include:-
 - **General Laboratory Request Form (PL001)** is used for most Biochemistry, Haematology, Immunology, Serology/Virology blood tests.
 - **Microbiology Form (PL002)** is used for Urines, Swabs, Sputum, Blood cultures, Faeces and Cerebrospinal Fluid (CSF) specimens.
 - **Histopathology Request Form** is used for Histopathology specimens (**Form no. 425**)
 - **Blood Transfusion Form (PL003)** is used for Blood Bank requests.
 - **Troponin-I Form (PL005)** (in-house use only)
 - **Mantoux Form** (in-house use only)
 - **Allergy Request Form (PL006)**
 - **Histopathology Request Form – Breast Biopsy (PL007)**
 - **Creutzfeldt Jacob Disease / Protein 14-3-3 Request Form for CSFs (PL008)**
 - **Gynaecological Cytology Claymon Biomnis Laboratories Request Form**
 - **Claymon Biomnis Genetic Test Request Form (Form RQF 36)**
- Where our customers use a non prescribed form, the Pathology department (Specimen Reception) accepts the request for Laboratory services provided on inspection of form/ specimen/ quality parameters the defined requirements of procedure BSC/PATH/SOP/030 titled “**Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens**” are met.
- Our acceptance of any contract is based on the incoming inspection process as described above. Reference procedure BSC/PATH/SOP/030 titled “**Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens**”.
- On rejection of a contract (failed incoming inspection), the customer is informed and a repeat specimen may be requested as per the requirements of procedure BSC/PATH/SOP/030. All rejected contracts are documented on attachment 7.2 “**Log of Specimen Reception Specimen/ Form Issues**” of procedure BSC/PATH/SOP/030.



- **The contract review process includes the following:-**
 - Analysis of contractual issues based on:-
 - a) Monthly reports on Laboratory Specimen/ Form issues
 - b) Feedback from Medical/ Nursing personnel

The above are discussed at the quarterly Laboratory User Group meetings and at the monthly Best Practice meetings. The specimen/ form issues report is circulated to the Nurse Practice Development Officer who distributes the reports to each Clinical Nurse Manager.
 - Analysis of Customer Surveys

Customer surveys are performed by the Pathology department. At least one survey is performed per year. Results and key objectives traceable to the output of the surveys are reviewed at the **Monthly Laboratory Quality Assurance Meeting** and the **Annual Management Review** meeting.
 - The Laboratory Services Manager reviews the contractual arrangements with external customers on at least an annual basis. A file of this review is maintained in a file titled “External Customer Contract Review”. The external contract review file records for each contract review the following:-
 - Name and position of external customer
 - Date/ time of contract review
 - Method of contract review e.g. phone, person to person, teleconference
 - Finding of meeting
 - Action items
 - Date agreed action items close out
 - Date reviewed by accreditation meeting
 - Signature of Laboratory Services Manager
 - Review at quarterly point of care meetings
 - Customer Complaints
 - Review of transfusion practice via "The Hospital Transfusion Committee Meeting". The meetings are held regularly and minutes are taken.
 - Review of the suitability of the test request form (forum for this is the quarterly Laboratory User Group meeting).
- The above review processes feed into the Quality Management Review process. Refer to section 4.15. Reference procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”.
- Where these reviews lead to changes in existing arrangements (for new examination procedures or changes to existing examination procedures) and prior to making any change Laboratory Management should ensure:-
 - a) - That the test method has been documented, verified and approved and is comparable with the existing method and meets the manufacturers specification. Reference procedure BSC/QA/SOP/058 titled “**Procedure for the Validation of Test Methods**”.
 - That an internal quality control programme and external quality assessment scheme is defined, documented and in place. Reference to procedure BSC/QA/SOP/024 titled “**Performance and Review of Internal Quality Control and External Quality Assessment Samples**”.



- b) That the Laboratory has the capability in terms of method, materials, personnel, equipment and environment to meet the new or amended requirements.
 - c) That from a clinical perspective the changes meet the clinical needs of the patient. The relevant Laboratory Consultant will verify in the Change Control documentation that the change meets clinical requirements. Refer to procedure BSC/QA/SOP/054 titled **“Procedure for the Control of Change to Equipment, Processes, Techniques and Controlled Documentation”**.
- It is the policy of the Pathology department not to sub contract any Haemovigilance or Traceability activities.

4.4.2 Records of contract reviews (traceable to 4.4.1) are maintained and include:-

- Minutes of meetings
 - Monthly Best Practice
 - Monthly Laboratory Quality Assurance meeting
 - Hospital Transfusion Committee Meetings
 - Quarterly Laboratory User Group Meetings
 - Quarterly point of care meetings
- Log of Specimen Reception/ Form Issues including the monthly report (Head of Department Specimen Reception)
- Customer Survey (Laboratory Quality Assurance Officer)
- Customer Complaints (Laboratory Quality Assurance Officer)
- Change Control Request Forms (Laboratory Quality Assurance Officer)
- External Customer Contract Review File (Laboratory Services Manager)
- Test Request Forms

4.4.3 It is the policy of the Pathology department **not** to refer accredited tests or tests within the scope of accreditation to external Laboratories (International Standard **ISO 15189**). However, in limited circumstances specimens may be referred. Refer to section 4.5 of this document “Examination by Referral Laboratories”.

4.4.4 Customers (internal/ external) are informed in advance of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced on the instruction of either party, the same contract review process as relevant and as described in section 4.4.1 is repeated and any amendments are communicated to the internal/ external customer. This amendment is recorded by L.I.S. For example, an initial test request for group and hold is amended to group and crossmatch. Refer to procedures BSC/PATH/SOP/030 titled **“Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens”** for procedures as it applies to non Blood Transfusion add on tests and procedure BSC/BB/SOP/001 attachment 7.1 titled **“Blood Bank Change of Order Log”** for Blood Transfusion add on tests.



4.5 EXAMINATION BY REFERRAL LABORATORIES

- 4.5.1
- a) It is the policy of the Pathology Department not to refer tests within the scope of accreditation (International Standard ISO 15189) to external laboratories.
- b) However, the following limited circumstances may require the referral of accredited tests to selected external laboratories or to external Medical Consultants who provide second opinions on Histopathology samples:-
- following equipment breakdown and where urgent specimens must be processed and resulted immediately and where a back up methodology is not available or practicable.
 - where external serological investigations are required to confirm or identify a pattern of results i.e. complex antibody investigation including provision of compatibility services.
 - where the test is urgent and cannot be performed out of hours i.e. staff or patient needlestick injury requiring immediate assessment of virology marker status.
 - where to confirm a final diagnosis the Consultant Histopathologist refers Histopathological samples to an external Consultant Pathologist for a second opinion.
- c) The Pathology Department has a documented procedure for evaluating and selecting referral laboratories as well as Consultants who provide second opinions for Histopathology.
Reference: BSC/QA/SOP/025 titled "**Evaluation and Selection of Referral Laboratories and Consultants who Provide Second Opinions**"
BSC/QA/SOP/026 titled "**Control of Service System Non Conformances**"
- d) Laboratory Management with respect to the procedures defined in (c) above are responsible for selecting and monitoring the quality and competency of referral laboratories and consultants on an ongoing basis.
- 4.5.2
- Laboratory Management has set up Service Level Agreements with referral laboratories. The agreement is normally for three years and requires review thereafter. These arrangements ensure that:-
- Requirements including the pre examination and post examination procedures are adequately defined documented and understood.
 - The referral laboratory is meeting these requirements.
 - The methodologies used by the referral laboratory are approved.
 - Responsibilities for interpretation, release and reporting of results are clearly defined and understood by both parties.
 - Records of Service Level Agreements and reviews are maintained.
- 4.5.3
- The Laboratory maintains an electronic listing (register) of the referral laboratories it uses including external consultants.
- The name and location of the referral laboratory is identified with the test result issued by the Pathology Department (Bon Secours).
 - A duplicate copy of the transcribed test result is retained in the patient file (hardcopy) and in the permanent file of the laboratory (electronic).



- 4.5.4** The Pathology Department (Bon Secours) are responsible for ensuring that the requesting clinician (internal/external) receives the test report. The test report issued will:
- meet the requirements of clause 5.8.3 (a-n) of ISO15189.
 - contain a comment describing where the test was performed and the reason for referral i.e. equipment failure.

4.6 EXTERNAL SERVICES AND SUPPLIES

- 4.6.1**
- Laboratory Management define practice for the selection and use of purchased external services, equipment and consumables considered to be **critical** to the delivery of its service. This includes Haemovigilance and Point of Care testing services. Refer to attachment 7.1 of procedure BSC/PATH/SOP/050 titled "**List of Approved Critical Suppliers of Products/ Services**". Vendors of product or service are approved on the basis of satisfactory completion and review of survey documentation, refer to attachment 7.2 titled "**Vendor Questionnaire**" of procedure BSC/PATH/SOP/050.
 - A master list of **critical equipment, consumables and external services** is maintained.
 - The master list of equipment and critical services related to same is maintained on the Hospital Asset Management System (HAMS) as per procedure BSC/QA/SOP/040 titled "**Procedure for the Control of Pathology Equipment Including Service Contracts**". It is the responsibility of the Laboratory Quality Assurance Officer/ Validation Technician to manage the Laboratory Asset Management System.
 - It is the responsibility of Heads of Scientific Departments to define, maintain and manage a master list of critical consumables/ reagents and external critical services.
 - Furthermore, such critical items will consistently meet the specified quality attributes. To achieve consistency Purchase Requisition/ Order documentation states:-
 - Type, grade, class etc. of the Material/ Equipment/ Service to be purchased are clearly and uniquely defined (as appropriate).
 - National/ International standard/ in-house standard to which Material/ Equipment/ Services are clearly defined (as appropriate).
 - Packaging requirements are clearly defined (as appropriate).
 - Any labelling requirements are clearly defined (as appropriate).
 - Shelf-life requirements are clearly defined (as appropriate).
 - Instructional information (user) is clearly identified by attachment or enclosed product inserts (as appropriate).
 - Departmental procedures are in place for the inspection/ acceptance rejection and storage of consumable material.
- 4.6.2**
- The policy of the Bon Secours Pathology Department is that a documentation check be performed **on all critical in-coming materials/ supplies** before being used in the testing process. Furthermore, as appropriate or practical, new lots of QC material should be verified as satisfactory prior to being released into routine use.
 - Critical materials used for test and inspection are appropriately stored.



- Critical materials or services not meeting our requirements are rejected. Rejected materials are stored in a location distinct from suitable materials.
- Purchased critical equipment are not used until verified as complying with our requirements. Refer to procedure BSC/QA/SOP/040 titled “**Procedure for the Control of Pathology Equipment Including Service Contracts**” and BSC/QA/SOP/058 titled “**Procedure for the Validation of Test Methods**”.
- The status of critical incoming materials are identified by status labelling.
 - Released for Use
 - Quarantine (Do Not Use)
 Where the material is not labelled, it means that material is not inspected and is therefore not released for routine use. These status labels are used by all scientific departments.
- It is the policy of the Bon Secours Hospital to have contracts in place with suppliers of critical services.

4.6.3

- An inventory control system is in place to manage the supply and use of critical supplies.
- The Laboratory maintains for critical supplies, materials and equipment the following data :-
 - Date received in the Laboratory.
 - Date material used.
 - Lot number and expiry date as appropriate.

4.6.4

A master list of approved critical suppliers of service and materials is maintained by each Head of Scientific Department. Suppliers of critical external service and supplies (material) are evaluated. This evaluation is based on review of non-conformance reports traceable to equipment, materials and services. This evaluation is performed by the Laboratory Quality Assurance Officer and Heads of Department. Results of these evaluations are documented. Suppliers consistently not meeting our requirements may be removed from the approved suppliers lists. Refer to procedure BSC/PATH/SOP/050 titled “**Procedure for the Purchase of Critical Products/ Services**”.

4.7 ADVISORY SERVICES

- The Laboratory Medical and Scientific staff provide an extensive advisory service. Refer to section 3.0 of document BSC/PATH/GDE/001 titled “**Primary Sample Collection Manual**”. This advisory service includes Laboratory Medical Consultant and scientific advice on the full range of tests and diagnostic services provided as well as the Haemovigilance advisory service. Refer to Figure 1 section 4.1.2 of this document.
- Meetings between representatives of professional Laboratory staff, internal hospital clinical staff are regularly held. Refer to the minutes of the Hospital Transfusion Committee meetings and Hospital Best Practice meetings. These records are electronically stored in the shared area under the control of the Quality Assurance Office. The purpose of such meetings is to ensure the best possible delivery of service.



- The Consultant Pathologists participate in a number of different Hospital Multidisciplinary Team meetings where selected cases are reviewed. Records of attendees as well as details of cases reviewed are maintained by the Pathology Office.
- The Point of Care committee provides advisory services on the selection and control of POC testing services, refer to minutes of meetings.
- The National Haemovigilance Office provides advisory services for Blood Transfusion and Haemovigilance activities including:-
 - Provision of Best Practice Guidelines
 - Information from the National Haemovigilance Conference (Ongoing Education)
 - Provision of advice following notification of serious adverse events and reactions
- The Irish Blood Transfusion Service provide an advisory service and act as a reference centre for clinical and scientific transfusion issues.

4.8 RESOLUTION OF COMPLAINTS

- The Laboratory documents all perceived or real grievances from Clinicians, patients or other related parties and investigates as formal complaints. Records of all complaints including appropriate investigations and corrective actions taken by the Laboratory are reviewed and maintained. Complaints may relate to Haemovigilance and Traceability as it applies to the Hospital Blood Bank and Point of Care testing services.
- The Pathology Department is committed by use of surveys or otherwise to establishing a method of measuring customer satisfaction. At least one survey will be performed annually.
- The customer complaints process and outputs are reviewed at the monthly quality meetings. The customer complaints process is controlled by procedure BSC/QA/SOP/028 titled "**Complaints Handling System**".
- The output of these processes form part of the Quality Management Review process. Refer to section 4.15.
- Records of this activity are maintained as per the requirements of procedure BSC/QA/SOP/009 titled "**Procedure for the Control of Archive Documentation, Specimens and Preparations**".

4.9 IDENTIFICATION AND CONTROL OF NON-CONFORMITIES

- ### 4.9.1
- Laboratory Management have documented procedures in place when it detects
 - That any aspect of its examination/ testing procedures do not perform as expected.
 - That the stated Quality Management requirements are not met.
 - That the requirements of the clinician are not met.
 - Haemovigilance/ blood component traceability requirements are not met.



- The identification and control of non-conformities is managed by the following procedures:-

BSC/QA/SOP/028	Complaints Handling System
BSC/QA/SOP/030	Internal Quality Audit Procedure
BSC/PATH/SOP/030*	Procedure for the Receipt, Checking, Computer Registration, Secondary Processing including Labelling and Distribution of Pathological Samples
BSC/PATH/SOP/035*	Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Histopathology Specimens on CoPath
BSC/IT/SOP/007	Reporting Laboratory Information System (LIS) Errors by Pathology Staff
BSC/QA/SOP/026	Control of Service System Non Conformance
BSC/HV/SOP/002	Management of Haemovigilance Events in the Hospital

* Where the specimen/ form issues identified are clinically significant, then a non conformance must be written as per the requirements of procedure BSC/QA/SOP/026 titled "Control of Service/ System Non Conformance".

- Non-conforming events may relate but are not limited to:-
 - the delivery of the testing service e.g. turnaround times
 - critical materials used in the testing service
 - the receipt and delivery of samples/ specimens.
 - sample bottles including labelling requirements.
 - failures in equipment associated with the testing process.
 - equipment calibration, cleaning and decontamination processes.
 - internal and external audit reports
 - quality control checks
 - management review
 - third party assessment schemes
 - amended test reports
 - Haemovigilance and blood component traceability issues and adverse events/ reactions as it applies to transfusion practice.
 - compatibility labelling of blood/ blood components
 - Point of Care testing services.
- **These procedures ensure** that:-
 - a) Personnel/ department responsible for problem resolution are designated.
 - b) the actions to be taken are defined (corrective/ preventative).
 - c) the medical significance of the non conforming examinations is considered and where appropriate, the requesting clinician informed (the impact on the patient).
 - d) test is halted and reports withheld as necessary.
 - e) corrective action is taken immediately.
 - f) the results of non conforming test results already released are recalled or appropriately identified, if necessary.
 - g) the responsibility for authorisation of the resumption of testing is defined
 - h) each episode of non conformity is documented and recorded, with these records being reviewed at regular specified intervals by Laboratory Management to detect trends, initiate preventative action or set objectives which feed into the Quality Management review process. Refer to BSC/QA/SOP/020 titled "**Procedure for Quality Management Review**".



i) the event is clearly described (i.e. equipment/ test method/ material involved in the non conformance).

- Records of non conforming events including investigations are retained as per the requirements of procedure BSC/QA/SOP/009 titled **“Procedure for the Control of Archive Documentation, Specimens and Preparations”**.

4.9.2 Where following investigation/ review of a non conforming test validity event, a doubt is raised that the incident could recur, then troubleshooting methods are employed so as to identify, document and eliminate the root cause of the issue. This corrective action is promptly implemented. Reports traceable to such an event are attached to the non conformance documentation.

4.9.3 Where a non-conformance investigation validly questions the accuracy or trueness of reported results, then the relevant Medical Consultant or nominee of same must only release such results having authorised same by documenting as a planned deviation (non-conformance).

4.10 CORRECTIVE ACTION

4.10.1 Systems and procedures used by the Pathology Department to identify and control non-conformities, as described in section 4.9, ensure where appropriate an investigative process to determine the cause of the problem is in place. The nature of the corrective action depends on the classification of the non-conformity and on the magnitude of the risk to the final customer (the patient).

4.10.2 Where corrective action proposes change, then such change is authorised as per the requirements of procedure BSC/QA/SOP/054 titled **“Control of Change to Equipment, Processes, Techniques and Documentation”**.

4.10.3 Procedures for corrective action include investigation and documentation of the causes of non-conformances. Laboratory Management ensure by review that corrective actions taken are effective by reviewing repeatability rates. Such reviews are incorporated into the monthly quality assurance meetings and the annual management review meeting and or any other meetings as called by the Laboratory Management to investigate and close out serious quality incidents.

4.10.4 Where the identification and investigation of non-conformances or the corrective actions performed therein implies non-compliance with the stated policies and procedures of the Quality Management System, then the quality management team at their discretion direct that the appropriate areas or activities are audited. The results of such audits are part of the quality management system review.



4.11 PREVENTATIVE ACTION

4.11.1 Laboratory Management are **proactive** in identifying opportunities for improvement rather than reacting to stated complaints or non-conformances. The Laboratory Services Manager, Heads of Department and Medical Consultants are responsible for identifying the potential sources of non-conformities which may relate to the Quality Management System or to Technical aspects of the provision of service. Examples of preventative action may include enhancement of the security system, improving the queuing system for Laboratory out-patients and measurement of customer satisfaction.

4.11.2 The Quality Management Review process may determine preventative action as appropriate based on review of predefined activities as set down in the annual Quality Management Review process. Refer to section 4.15.

4.12 CONTINUAL IMPROVEMENT

4.12.1 All standard operating procedures as per the requirements of the document control system are reviewed at periods not greater than two year intervals. The purpose of such review is to identify potential sources of improvement in Quality Management or Technical Practices. All proposed changes are documented as per the requirements of procedure BSC/QA/SOP/054 titled “**Change to Equipment, Processes, Techniques and Documentation**”.

4.12.2 Actions taken to improve the quality of service are reviewed for effectiveness. Such reviews include monitoring the levels of non-conformances traceable to the area or activity the quality improvement action is associated with.
With respect to point of care testing, continuous improvement is verified by annual monitoring or audit of one of the following:-

- Monitoring of point of care testing ordering patterns
- Monitoring record keeping
- Review of critical value reports (where they apply)

4.12.3 Based on the review of non-conformances, Laboratory Management may direct as appropriate any further changes to the Quality Management System required.

4.12.4 Laboratory Management is committed to the use of surveys in order to establish a method of measuring the Laboratory’s contribution to patient care. Where such surveys identify opportunities for improvement, Laboratory Management is committed to taking all necessary steps to ensure such opportunities for improvement are taken. Furthermore, Laboratory Management avails of all relevant opportunities to ensure participation in Hospital Quality Improvement Activities whose objective is to improve patient care, for example, participation by the Blood Transfusion Laboratory/ Haemovigilance office in an ongoing quality monitoring programme.

4.12.5 Laboratory Management is committed to continual improvement by means of providing all necessary and suitable education and training opportunities to Laboratory and Haemovigilance personnel. Refer to procedure BSC/QA/SOP/010 titled “**Control of Training in the Pathology Laboratory, Bon Secours Hospital**”.



4.13 QUALITY AND TECHNICAL RECORDS

- 4.13.1 - Laboratory Management establish and implement procedures for the control of quality and technical records. Such procedures control the identification, collection, indexation, access, storage, maintenance and safe disposal of such records. This activity is controlled by the following procedures:-

BSC/QA/SOP/001	Document Numbering System
BSC/QA/SOP/005	Operation of a Controlled Document System
BSC/QA/SOP/007	Completion and Retention of Quality Records
BSC/QA/SOP/008	Procedure for the Control of Archive Laboratory Documentation and Histopathology Material including Tissue Blocks and Slides
BSC/QA/SOP/009	Procedure for the Control of Archive Samples and Documentation
Report of the Working Party of the Royal College of Pathologists and the Institute of Biomedical Science (Current Version)	The Retention and Storage of Pathological Records and Archives
	NHO Code of Practice on Medical Records
	INAB (Irish National Accreditation Board) Guidelines and Recommendations
	EU Directive 2002/98/EC titled "Setting 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.

- Laboratory Management are committed at a minimum to meet the recommendations of the Royal College of Pathologists as they apply to the retention and storage of Pathological records and specimens.

4.13.2 All records should be legible and stored in such a way that they are readily retrievable. To assist legibility of completed records, all staff are trained in the completion of controlled documents as per the requirements of procedure BSC/QA/SOP/007 titled **“Completion and Retention of Quality Records”**. Records are stored on hard copy and by electronic means. Laboratory Management take all possible steps to ensure that technical records are stored in an environment that prevents damage, deterioration or unauthorised access. Refer to procedures BSC/PATH/SOP/040 titled **“Security”** and BSC/QA/SOP/008 titled **“Procedure for the Control of Archive Laboratory Documentation and Histopathology Material including Tissue Blocks and Slides”**.

4.13.3 Retention times for Quality and Technical records are defined by the Clinical Director. The minimum retention times are compatible with the recommendations of the Royal College of Pathologists as stated in document titled **“The Retention and Storage of Pathological Records and Archives” current version**. A master listing of Quality and Technical records is defined in procedure BSC/QA/SOP/009 titled **“Procedure for the Control of Archive Sample and Documentation”**.

The following is a list of records (documents) and their associated minimum retention times. This listing applies to all departments except Blood Transfusion.



ID	Document Description	Minimum Retention Period
a.	Request Form Request Form used to record:- - Working notes - Results or - Interpretative data (Histopathology/ specimens and slides)	1 month after authorisation of report At least 30 years
b.	Reports (copies) - A report can be reprinted electronically at any time. - Softcopy Refer to BSC/QA/SOP/009 for further details	At least 30 years
c.	Instrument printouts where the instrument is not backed up electronically	At least 5 years
d.	Standard Operating Specifications, Procedures, Policies, Plans, Standards (Master/ Obsolete documents), Service Contracts	At least 5 years
e.	Workbooks with raw data on named patients	At least 5 years
f.	Records of specimen receipt (Electronic Record)	At least 30 years
g.	Calibration functions and conversion factors	At least 5 years
h.	Quality Control records	At least 5 years
i.	Change Controls, Complaints and Non- Conformance Records	At least 5 years
j.	Internal/ External Audit Reports	At least 5 years
k.	External 3 rd party quality assessment records	At least 5 years
l.	Quality Improvement Records	At least 5 years
m.	Equipment Cleaning and Maintenance - Manuals - Logbooks etc - Calibration records	Retained for lifetime of instrument plus 10 years
n.	Package inserts/ certificates of supplies	At least 5 years
o.	Incident/ Accident records	At least 30 years
p.	- Job Descriptions - Training Records procedural - Training Records external - Qualifications - Competency	Working life of the employee
q.	Consent Forms	At least 30 years



ID	Document Description	Minimum Retention Period
r.	Records of Telephoned Reports	At least 5 years
s.	Correspondence to Patients	At least 30 years
t.	Point of Care (Near Patient Test Results)	At least 30 years
u.	Minutes of HOD and Quality Meetings	At least 5 years

Control of Archived Documentation (Blood Transfusion)

ID	Document Description	Minimum Retention Period
1.	Request form for blood grouping, antibody screening and crossmatching	At least 30 years
2.	Traceability and Haemovigilance records (worksheet) for blood products. Hardcopy/ electronic. (Ref. EU Directive 2002/98/EC)	At least 30 years
3.	Results of blood grouping, antibody screening and other blood transfusion related tests. ((Ref. EU Directive 2002/98/EC)	At least 30 years
4.	Blood bank register, blood component audit trail and fates. Traceability of donor and recipient. Hardcopy/ electronic. (Ref. EU Directive 2002/98/EC)	At least 30 years
5.	Refrigerator and freezer charts	15 years
6.	Records of adverse events	15 years

4.14 INTERNAL AUDITS

4.14.1 The Quality Management team have established and maintain documented procedures for planning and implementing internal quality audits so as to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. All elements of **ISO 15189** are audited (management and technical requirements) on an annual basis as well as activities exclusively under the control of the Blood Directive (2002/98/EC) and AML-BB requirements. The schedule and scope of internal audits are pre defined in that the Laboratory Quality Assurance Officer issues “**An Annual Internal Audit Schedule**” for the next year. Reference BSC/QA/SOP/030 titled “**Internal Quality Audit Procedure**”.

Note: The audit schedule includes vertical audits of the Haemovigilance activity by tracking blood components from receipt to transfusion.

- 4.14.2** - Internal audits are:-
- Planned and organised by the Laboratory Quality Assurance Officer.
 - Performed by the Laboratory Quality Assurance Officer/ trained nominee.



- The procedure controlling this activity, reference BSC/QA/SOP/030 titled “**Internal Quality Audit Procedure**” defines the following:-
 - The frequency and type of audit (vertical and horizontal).
 - The planning of an internal quality audit.
 - The performance of the audit.
 - Classification of non conforming events as major or minor.
 - The entry and exit meeting process (for those involved pre and post the audit).
 - The reporting activity including interval between audit and report and close out of issues.
 - The mechanism for close out of non conforming issues.
 - The documentation traceable to the internal audit process.
 - That follow up is performed to ensure that the stated corrective actions have been taken and that such actions are effective.
 - That the Laboratory Quality Assurance Officer authorises audit reports.
 - That audit reports are issued to the:-
 - Clinical Director
 - Laboratory Services Manager
 - Relevant Medical Consultant
 - Relevant Head of Department
 - That records of this activity (audit schedule, audit checklist, audit report and audit non conformances) are maintained as per the requirements of procedure BSC/QA/SOP/009 titled “**Procedure for the Control of Archive Documentation, Specimens and Preparations**”.

- The audit report defines the agreed corrective and preventative actions that must be carried out within agreed timelines.

The audit activity will be reviewed as a standard item at the Quality Management Review Meeting. Refer to procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”.

4.15 MANAGEMENT REVIEW

4.15.1 - Quality Management Review

The Laboratory Management team reviews the Laboratories Quality Management System at least on an annual basis. This review **incorporates provision of Medical Services including examinations and advisory services**, to ensure that the Laboratory continues to be **suitable** and **effective** in **support** of **patient care** and to introduce any necessary changes or improvements. This activity is controlled by procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”. The scope of the Management Review applies to services described in fig. 1 of section 4.1.2.

- Results of Quality Management Review

The results of the review clearly identify and document for each area or activity reviewed the following:-

- Current status.
- Clearly defined goals and objectives.
- Timeline to achieve the stated goals and objectives.



The goals and objectives set at the previous Quality Management review meeting are revisited at the next Quality Management Review Meeting so as **progress versus plan** can be measured.

- The Annual Quality Management Review meeting is chaired in rotation by the Laboratory Services Manager and the Clinical Director. The meeting is attended by:-
 - Laboratory Medical Consultants x 5
 - Heads of Department x 7
 - Laboratory Quality Assurance Officer
 - Laboratory Information System Manager
 - Haemovigilance Nurse
 - **Diabetes Nurse Specialist**
 - Validation Technician

- **Day to Day Quality System Management**
 A planned monthly meeting will take place to manage the day to day quality system events. A minimum of 10 meetings will be held on an annual basis. The purpose of this meeting is to review on a monthly basis the following standard items:-
 - Matters arising from minutes of the previous meeting.
 - Actions and decisions of the previous meeting.
 - Review of sample/ form non conformances
 - Review of third party external quality assessment programmes (EQA).
 - Review of test turnaround times.
 - Review of customer complaints.
 - Review of internal service system non-conformances.
 - Review of change management.
 - Review of Laboratory Information System (LIS) Errors.
 - Review of internal or external audit reports.
 - Hospital Accreditation (JCI) update.
 - Review of clinical issues.
 - Management update.
 - Head of Departments Health and Safety update.
 - Validation Technician equipment update.
 - Any other business.

This meeting is attended by the Laboratory Services Manager, Laboratory Consultants, Laboratory Information System Manager, Laboratory Quality Assurance Officer, Heads of Department and Validation Technician . The decisions of the meetings are recorded. The Laboratory Quality Assurance Officer is responsible for maintaining records of this activity including copies of all generated reports. This activity is controlled by procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”.

- **Head of Department Meetings**
 Heads of Department meetings are scheduled monthly. A minimum of 10 meetings will be held on an annual basis. Records of the decisions of these meetings are maintained by the Laboratory Services Manager. This meeting is chaired by the Laboratory Services Manager. This activity is controlled by procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”.



- **Clinical Management Meetings**

The Clinical Management Meetings are held at least on a quarterly basis. The meeting is chaired by the Clinical Director. This meeting is attended by the Laboratory Consultants, Laboratory Services Manager, Chief Medical Scientist / Nominee, Laboratory Quality Assurance Officer and other Heads of Department depending on the agenda. This activity is controlled by procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”.

- **Laboratory Users Group Meetings**

The Laboratory User Group Meetings are held on a quarterly basis. This meeting is chaired by the Senior Medical Scientist, Microbiology. The meeting is attended by the Laboratory Services Manager, Laboratory Quality Assurance Officer, Consultant Pathologist x 1, Nursing Practice Developing Officer, Clinical Nurse Managers from Medical and Surgical Wards, a NCHD Representative and other personnel depending on the agenda. This activity is controlled by procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”.

- **Point of Care Meetings**

The Point of Care Committee Meetings are held every **six months and if clinically required**. The meeting is chaired by the Chemical Pathologist. This meeting is attended by the Chief Medical Scientist (Biochemistry), Nursing Practice Developing Officer, Clinical Services Co-ordinator, Validation Technicians, Diabetes Nurse Specialist and other personnel as invited by the chairperson. This activity is controlled by procedure BSC/QA/SOP/020 titled “**Procedure for Quality Management Review**”.

4.15.2 The Quality Management Review Meeting will review the following activities:-

- a) **Follow up** of the previous Management review meeting.
- b) Status of **corrective actions taken** and required **preventative action** which is achieved by review of non-conforming events in terms of summary and analysis of customer complaints, internal service non-conformance reports and any other non-conformance system reports as appropriate.
- c) Report from the Laboratory Services Manager/ nominee focusing on:-
 - **Review of the Change Control process** including introduction of new technology, processes and tests including changes in the volume and type of work undertaken, refer to g.
 - **Review of new or amended regulatory requirements**, accreditation requirements, standards and specifications and the impact if any of any new or amended requirement would have on the delivery of service by the Pathology Laboratory.
- d) The findings and status of **recent internal audits** (since the last Management Review meeting).
- e) Assessment by **external bodies** (NAB and **ISO 15189**).
- f) Review of performance as it applies to participation in **external quality assessment schemes** traceable to the following departments or activities, Histopathology, Microbiology, Haematology/Blood transfusion and Biochemistry. Each Head of Department will produce a report on their respective external quality assessment performance.
- g) Any changes in the **volume and type of work** undertaken, refer to c.
- h) **Feedback from clinicians**, patients and other parties incorporating:-
 - Review of customer complaints
 - Review of customer satisfaction surveys
 - Review of contracts (external to the hospital)



- i) Quality indicators for monitoring the Laboratories contribution to patient care.**
The Laboratory Medical Consultants review and report through the Clinical Director on the Quality and Appropriateness of the Laboratories contribution to patient care. This report should identify any necessary changes or proposed amendments that would assist the Hospital Clinicians in the enhancement of Clinical services. The following indicators should contribute to this report:-
- Results of patient/ customer surveys (refer to h).
 - Adequacy of test turnaround time (refer to h).
 - The use and effectiveness of the “**Primary Sample Collection Manual**” BSC/PATH/GDE/001.
 - Output from the Hospital Transfusion Committee meetings as it relates to the quality of service provided. The quality of the service is measured by a review of quality indicator data as well as a review of adverse reactions and events. (Report presented by the Chief Medical Scientist/ Haemovigilance Nurse).
 - External contract review reports.
- j) Non Conformities** (refer to b)
- k) Monitoring of turnaround time.** The Chief Medical Scientists present an overview of this activity relevant to their area of activity.
- l) Results of continuous improvement processes including:-**
- Procedural update.
 - Corrective and preventative actions taken (refer to b and j).
 - Actions taken as a result of customer satisfaction surveys.
 - Review of the annual training education programme.
- m) Evaluation of suppliers including referral laboratories.** This process forms part of the review of non conformities (j) and their status as it relates to corrective and preventative actions (b).
- n) Update of Hospital Health and Safety meetings.** This report is presented by a nominated Head of Department.
- o) Review of Laboratory User Group Meetings.**
- p) Review of point of care testing activity**

4.15.3 The quality and appropriateness of the Laboratory's contribution to patient care is monitored and evaluated objectively. The Clinical Director presents a report as an item agenda at the Quality Management Review meeting.

4.15.4 The findings of the Quality Management Review Meeting are documented as minutes. The Laboratory Quality Assurance Officer is responsible for maintaining records of this activity including copies of all generated reports. The findings of the Quality Management Review Meeting are made available for review by Laboratory personnel. The Laboratory Director ensures that agreed actions/decisions taken at the Quality Management Review meeting are acted on within the defined timescale. The agreed quality objectives are monitored on a quarterly basis at the monthly Quality Assurance meetings.



5.0 TECHNICAL REQUIREMENTS

5.1 PERSONNEL

- 5.1.1**
- Approved **written job descriptions** are in place for all grades of personnel (scientific, medical, Haemovigilance Nurses and support services as defined in fig. 1 of section 4.1.2).
 - Job descriptions are reviewed annually during the Performance Review and Development (PRD) process and changed accordingly in agreement by both parties.
 - All new staff undergo induction training. Induction training is controlled by the Personnel department. At induction new employees are made aware of and trained on the following personnel policies:-
 - **Disciplinary Procedure (Document No. HR0005).**
 - **Policy to Promote Dignity and Respect at Work (Document No. HR0004).**
 - **Patient/ Family Grievance Procedure (Document No. BP0009).**
 - **Corporate Compliance Plan: Code of Conduct (Document No. BP0030).**
 - **Gratuity Policy (Document No. BP0010).**
 - **Patient Privacy and Confidentiality Policy (Document No. BP0033).**
 - **E Mail and Internet - Appropriate Use Policy (Document No. HR0006).**
 - **Hospital Induction Policy - Infection Control, Human Resources, Occupational Health, Fire Training (Document No. HR0065)**
 - A separate Laboratory Induction Programme is in place and is controlled by procedure BSC/QA/SOP/012 titled "**Control of Pathology Procedural Training Including Laboratory Induction of New Staff**".
 - The organisational plan for the Laboratory is documented in attachment 6.1 of this manual titled "**Organisational Charts (Pathology/ Blood Transfusion Departments)**".
- 5.1.2**
- Laboratory Management or agents of same maintain **records of relevant educational and professional qualifications, training, competence and experience** of all personnel. These records include the following:-
 - a) **Certification or Licence**
A certification or license is not required by scientific personnel in order to practice.
 - b) **References From Previous Employment**
References from previous employment are maintained by the Human Resources Department.
 - c) **Job Descriptions**
Job descriptions are maintained by the Human Resources Department for Laboratory staff, by Nursing Administration for Haemovigilance staff and Diabetes Nurse Specialists by the Hospital Manager's office for Consultant staff.
 - d) **Records Of Continuing Education And Achievement.**
These records are maintained as external training records and are maintained and filed by the Laboratory Quality Assurance Officer, refer to attachment 7.1 of procedure BSC/QA/SOP/010 titled "**Control of Training in the Pathology Department, Bon Secours Hospital**".
Note: Blood Transfusion Laboratory and Haemovigilance Nurses as part of continuing education and achievement should attend NHO meetings, seminars and other professional meetings for continued professional development. This requirement will be reflected in the annual training plan.



e) **Competency Evaluation**

Competency records are maintained for staff as it relates to the scope of accreditation to **ISO 15189**. The records are maintained and filed by the relevant Chief Medical Scientist. Refer to procedure BSC/QA/SOP/018 titled "**Pathology Proficiency Testing of Laboratory Staff to Ensure Competency**". Records of competency evaluation are also maintained for Clinical personnel as it applies to meeting the requirements of EU Directive 2002/98/EC.

f) **Incident/ Accident Forms**

Records of personnel incidents/ accidents are maintained and stored by the Best Practice Department. Refer to Hospital policies BP0015 titled "**Incident Reporting**" and BP0017 titled "**Occurrence and Defect Reporting**".

g) **Qualifications**

Records of relevant scientific qualifications are maintained and filed by the Quality Assurance Office and the Human Resources Department.

h) **Other Records Relating To Personnel Health**

Other records relating to personnel health are maintained by the Occupational Health department.

5.1.3 - The **Laboratory is directed** by the **Laboratory Director** (Clinical Director and the Laboratory Services Manager). Refer to section 3.2 of this manual.

5.1.4 - The Laboratory Director (the Clinical Director and Laboratory Services Manager and nominees) have overall responsibility for:-

- The testing/ advisory including point of care testing and consultative services offered by the Laboratory.
- The administration of the department including management of personnel, and ensuring sufficient resources (human, material, equipment) are available to meet the requirements of the Laboratory services.
- Ensuring personnel are suitably qualified, trained and competent and for providing opportunities for continuing education.

- The Laboratory Director or designee for each task as described below, are trained and competent to be able to discharge the following:-



Task No.	Description of Responsibility	Responsible
a.	Provide advice on choice of test, use of Laboratory services and interpretation of Laboratory results or data. This includes point of care tests.	<ul style="list-style-type: none"> - Relevant Laboratory Medical Consultant. - Chief Medical Scientist
b.	Serve as an active member of the medical staff for the hospital.	<ul style="list-style-type: none"> - The Clinical Director and Laboratory Consultants are active members of the Hospital staff (Bon Secours Cork)
c.	Relate and function effectively with:- <ol style="list-style-type: none"> 1. National Accreditation Board 2. Hospital Manager 3. The healthcare community within the Hospital 4. The patient population served 	<ul style="list-style-type: none"> - Laboratory Services Manager/ Laboratory QA Officer - Laboratory Services Manager and Clinical Director. - The relevant Laboratory Medical Consultant - Hospital Manager/ Consultant Pathologist
d.	Define, implement and monitor standards of performance and quality improvements of the medical Laboratory service or services.	<ul style="list-style-type: none"> - Laboratory QA Officer (Quality Management). - The relevant Laboratory Medical Consultant and Chief Medical Scientist (Technical).
e.	Implement the Quality Management System	<ul style="list-style-type: none"> - Lead by the Laboratory QA Officer, the management team (4.1.5.1) manages the implementation and review of the Quality Management System. Refer to ISO 15189 (4.15). - A Laboratory Medical Consultant and Laboratory Services Manager participate as members of the Best Practice committee in Hospital quality improvement processes.
f.	Monitor all work performed in the Laboratory or at point of care to ensure reliable data is being generated and resulted (Internal QC and EQA).	<ul style="list-style-type: none"> - Relevant Chief Medical Scientist and the relevant Laboratory Medical Consultant. - Laboratory QA Officer
g.	Ensure personnel performing Laboratory tasks are suitably qualified, adequately trained and have the required experience.	<ul style="list-style-type: none"> - Laboratory Services Manager - Chief Medical Scientist/ nominee - Consultant Pathologists
h.	Plan, set goals, develop and allocate resources appropriate to the medical environment.	<ul style="list-style-type: none"> - Laboratory Management team lead by the Laboratory Services Manager. Refer to 4.1.5.1.
i.	Provide effective and efficient administration of the medical Laboratory services, including budget planning and control with responsible financial management.	<ul style="list-style-type: none"> - Laboratory Services Manager - Consultant Pathologists



Task No.	Description of Responsibility	Responsible
j.	Provide educational programmes for the Medical, Scientific and Haemovigilance staff and Diabetes Nurse Specialists ensuring participation in education programmes provided by the Hospital.	- Laboratory Services Manager - Director of Nursing
k.	Plan and direct research and development performed in the Laboratory (if applicable).	- Laboratory Services Manager - Relevant Laboratory Medical Consultant
l.	Select and monitor all referral Laboratories for quality of service.	- Chief Medical Scientists - Laboratory Quality Assurance Officer - Consultant Pathologists
m.	Implement a safe Laboratory environment in compliance with legal requirements, Hospital policy and Pathology department safety procedures.	- The Heads of Department reporting to the Laboratory Services Manager.
n.	Address any complaint, request or suggestion from the users of Laboratory services.	- Laboratory Services Manager - Consultant Pathologists
o.	Ensure good staff morale.	- Laboratory Services Manager - Heads of Department - Consultant Pathologists.
p.	Ensuring requirements of EU Directive 2002/98/EC are met.	- Consultant Pathologist (Dr. O'Murchu) - Laboratory Services Manager - Chief Medical Scientist (Haematology/ Blood Transfusion) - Laboratory Quality Assurance Officer

5.1.5 The Hospital Manager/ Laboratory Services Manager ensure that sufficient resources are available to meet the requirements of the Quality Management System. This includes a commitment to ensuring that staff resources are adequate for the work performed including Haemovigilance and blood component activities.

5.1.6 All personnel receive training in Quality Assurance and Quality Management for services offered.

- 5.1.7**
- Laboratory Management and Heads of Department ensures that only competent personnel perform critical operations.
 - The Chief Medical Scientist/ nominee authorises following training personnel to perform specific tasks such as:-
 - Testing procedure
 - Operation of test equipment
 - Use of Laboratory Information System (LIS)
 - The Director of Nursing/ Consultant Pathologist ensure that only competent trained staff are involved in the Blood Transfusion/ Haemovigilance/ Blood Component Traceability process.



- With respect to the use of the Laboratory Information System, the recommendations of Annex B of **ISO 15189 : 2003E** have been adapted as per the following:-
 - B2 **Environment (secure and clean)**
Refer to **BSC/IT/SOP/011** titled **“IT Central Room Computer Access”**
 - B3 **Procedure Manual(s)** (Use of Sunquest/ CoPath LIS Manuals).
 - B4 **System Security**
Refer to **BSC/IT/SOP/001** titled **“Laboratory Information System - User Registration (Network and Applications)”**
 - B5 **Data Entry and Reports**
Refer to **BSC/QA/SOP/058** titled **“Procedure for the Validation of Test Methods”**
BSC/PATH/SOP/060 titled **“Procedure for Review and Release of Reports to Users”**
 - B6 **Data Retrieval and Storage**
Refer to **BSC/IT/SOP/005** titled **“Saving Misys Transactions onto Tape Cartridge”**
BSC/IT/SOP/013 titled **“Procedure for Laboratory Information System Back Up, Tape Verification and Recovery”**
 - B7 **Hardware/ Software**
Refer to **BSC/IT/SOP/019** titled **“Procedure for Control of Hardware Preventative Maintenance”**
BSC/QA/SOP/054 titled **“Procedure For The Control Of Change To Equipment, Processes, Techniques And Controlled Documentation”**
 - B8 **System Maintenance**
Refer to **BSC/IT/SOP/009** titled **“Downtime Procedures – HIS + LIS”**
BSC/IT/SOP/003 titled **“Routine Maintenance of Laboratory Information System”**.

- A technical agreement is in place between the Hospital IT Manager and the Laboratory Information System Manager. This agreement clearly defines roles, responsibilities and interactions.

5.1.8

- Procedures have been established that define who may use the computer system including access to patient data and who is authorised to enter and change patient results, modify billing or computer programs. Refer to:-
 - **BSC/IT/SOP/001** titled **“Laboratory Information System - User Registration (Network and Applications)”**
 - **BSC/PATH/SOP/060** titled **“Procedure for the Review and Release of Reports to Users”**.
 - **BSC/QA/SOP/054** titled **“Procedure For The Control Of Change To Equipment, Processes, Techniques And Controlled Documentation”**.
 - Annex B of **ISO 15189 : 2003E** – **B4** System Security and **B5** Data Entry and Results.

5.1.9

It is the policy of the Laboratory Management to ensure an annual training plan is in place to ensure a continuing education programme. This training plan includes Haemovigilance Nurse requirements as well as point of care testing requirements. Refer to procedure **BSC/QA/SOP/010** titled **“Control of Training in the Pathology Laboratory, Bon Secours Hospital”**.



- 5.1.10** All personnel are made aware at induction of the method of reporting adverse incidents (personal accidents) specifically Haemovigilance staff are trained in the reporting of adverse events and reactions as it applies to Blood Transfusion. The reporting of adverse events in the Laboratory is controlled by Hospital policies BP0015 titled "**Incident Reporting**" and BP0017 titled "**Occurrence and Defect Reporting**".
- 5.1.11**
- The competency of personnel with regard to performing **testing** procedures is deemed to be satisfactory when the trainee has satisfactorily performed the procedure under supervision. On satisfactory completion of training including a proficiency assessment, the training event is recorded on attachments 7.1 of procedure BSC/QA/SOP/012 titled "**Control of Pathology Procedural Training Including Laboratory Induction of New Staff**" and attachment 7.2 of BSC/QA/SOP/018 titled "**Pathology Proficiency Testing of Laboratory Staff to Ensure Competency**".
 - The competency of all staff in line with their job descriptions, is formally reviewed on an annual basis by the Heads of Department by the Performance Review and Development (PRD) process. Results of this review are retained by the Human Resources department.
 - Retraining including proficiency assessment occurs as a corrective action following investigation of customer complaints or other non-conforming events. The retraining is performed in accordance with the requirements of procedure BSC/QA/SOP/014 titled "**Management of Re-Training Resulting from Non-Conformances, Customer Complaints or Audit Reports**".
 - Retraining including proficiency assessment occurs on an annual basis for staff performing emergency on-call duty. Refer to procedure BSC/QA/SOP/016 titled "**Training and Annual Re-Training for Pathology Emergency On-Call Duty**".
- 5.1.12**
- a. It is the policy of the Laboratory and specifically the Consultant Pathologists to have:-
- Written procedures are in place for the processing of all Histopathology specimens and for the reporting of surgical specimens under the scope of accreditation. These will be in accordance with the Faculty of Pathology – National Cancer Datasets and the Royal College of Pathologists "Standards and Minimum Datasets for Reporting Cancers" if available.
 - The Consultant Pathologists take part in regular professional development and will participate in the Medical Council Program for Continual Medical Development.
 - Periodically the Histopathology department may require a second opinion from external Consultant Pathologists. The criteria for their selection are based on meeting one or more of the following requirements:-
 - Availability
 - Experience/ expertise relative to the Pathology type requiring a second opinion.
 - Has specialised training
 - Professional qualifications (FRC Path) or equivalent
 - The availability of additional test methodologies such as immunohistochemistry and molecular techniques to assist in the diagnostic and interpretative process.
 - Proven track record in providing second opinions in a timely manner.
- Histopathology test reports identifies or references a second opinion. The selection process is controlled by the Consultant Pathologists. This listing for the external Consultants is maintained on a database by Document Control titled "Master List of External Histopathology Consultants"



- b. It is the policy of the Laboratory that Blood Transfusion/ Haemovigilance Nurses attend development programmes organised by the National Haemovigilance Office.

- 5.1.13** - Each employee is contractually bound to desist from divulging any patient information. Any breaches of this policy are fully investigated and appropriate censure taken.
- Furthermore, adherence to hospital policies reference document titled “**Confidentiality – Release of Patient Information**” document number BP0003 and document titled “**Confidentiality**” document number BP0005 ensures that patient confidentiality is strictly adhered to.

5.2 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

- 5.2.1** - The Laboratory and point of care testing operates so that its workload can be performed without compromising the quality of work, quality control procedures, safety of personnel or patient care services. The Laboratory Services Manager/ Director of Nursing ensures that the accommodation and environmental conditions are fit for their intended use and is maintained so as to continue to be functional and reliable.
- Primary samples are collected:-
- In the Laboratory outpatient facility
 - In the Hospital wards/ internal locations including theatre, hospital out patients, x-ray etc.
 - In external locations
- All testing is performed in the testing facility as defined in 4.1.1.
- 5.2.2** The design and workflow of the Pathology Department is such that there is a clear segregation between clerical, phlebotomy and laboratory areas. The purpose of such a design is to minimise the risk of injury and occupational illness and to protect employees and patients from recognised hazards.
- 5.2.3** The laboratory outpatient reception area and phlebotomy facilities are designed specially and take into consideration patients with disabilities. The design of the primary sample collection facility is such to ensure the optimisation of collection as well as affording the patient every comfort.
- 5.2.4** - The Laboratory design and environment is suitable for the tasks carried out therein. The environment in which the primary sample collection and examination (testing) takes place is controlled so that the results of any testing performed is valid.
- The Laboratory facilities are designed to have:-
- adequate lighting
 - adequate power supply (including contingency)
 - adequate ventilation
 - adequate water supply



- provision for adequate disposal of biological and non biological waste. Refer to procedure BSC/PATH/SOP/009 titled **“Segregation and Disposal of Waste (Including Biohazard Materials) from the Pathology Department”**.
- Environmental control is required and in place:-
- For fridges/ freezers/ incubators etc. (temperature) so that they operate within the defined specification. Refer to procedures BSC/PATH/SOP/071 titled **"Procedure for the Rees Centron Temperature Monitoring System (Laboratory Level)"**, BSC/PATH/SOP/072 titled **"Procedure for the Rees Centron Temperature Monitoring System (Administration Level)"** and BSC/PATH/SOP/070 titled **"Daily Temperature Monitoring of Pathology Department Temperature Controlled Equipment"**.
 - To ensure the weighing scales used to verify pipettes is free from vibration. Refer to procedure BSC/QA/SOP/052 titled **“Calibration of Pipettes/ Volume Delivery Equipment”**.
 - To ensure the Laboratory accommodation and environment is generally clean. Refer to procedure BSC/PATH/SOP/047 titled **“Household Cleaning in the Pathology Department”** and BSC/MIC/SOP/220 titled **“Environmental Monitoring”**.
 - To contain Risk Group Classification 3 and 4 Pathogen using a Containment Level 3 Laboratory. Refer to procedure BSC/MIC/SOP/212 titled **“Containment Level 3 Laboratory”**.
 - To ensure a quiet environment for critical operations by providing the Cytology Screener with a quiet segregated environment.
 - In the central computer room, a temperature monitoring system is in place. Refer to procedure BSC/IT/SOP/011 titled **“IT Central Computer Room Access”**.

Where the Laboratory facilities and its environment does not meet stated or understood requirements then such events are documented as internal service non-conformances in accordance with the requirements of procedure BSC/QA/SOP/026 titled **“Control of Service System Non-Conformance”**.

5.2.5 It is the policy of the Pathology Department to monitor, control and record environmental conditions as required. Where the data from such recording is out of specification and there is an impact on the quality of the product or service provided then a non-conformance form is completed and appropriate corrective and preventative actions taken. Refer to procedure BSC/QA/SOP/026 titled **“Control of Service System Non-Conformance”**. Procedures controlling the monitoring, review and recording of environmental data include:-

BSC/MIC/SOP/220 titled **“Environmental Monitoring”**
 BSC/MIC/SOP/212 titled **“Containment Level 3 Laboratory”**
 BSC/PATH/SOP/071 titled **"Procedure for the Rees Centron Temperature Monitoring System (Laboratory Level)"**
 BSC/PATH/SOP/072 titled **"Procedure for the Rees Centron Temperature Monitoring System (Administration Level)"**



5.2.6 There is effective separation between discrete Laboratory sections and activity so to prevent:-

- Incompatible activities operating in the one location
- Cross contamination

Refer to procedure BSC/MIC/SOP/212 titled “**Containment Level 3 Laboratory**” and **BSC/PATH/SOP/040** titled “**Security**”. The site map attached to this procedure shows segregation of activity.

5.2.7 Access to and use of areas affecting the quality of examinations is controlled. Security measures are in place to safe guard resources (material, equipment and personnel) from unauthorised access. Key pad access control is in place. Refer to procedure BSC/PATH/SOP/040 titled “**Security**”.

5.2.8

- Laboratory Management recognising the value of good communication systems within the laboratory have two electronic communication systems in place.
 - 1) Standard E-Mail system.
 - 2) E-Mailing system available as part of the standard Laboratory Information System software package (Misys).
- Heads of Department communicate all relevant issues by meetings or otherwise with personnel under their supervision.

5.2.9 Storage space is provided to ensure the continuing integrity for specimens, slides, Histopathology blocks, documents, manuals, equipments, reagents etc. Refer to procedure BSC/QA/SOP/009 titled “**Procedure for the Control of Archive Documentation, Specimens and Preparations**”.

5.2.10

- The Pathology Department work areas are clean and well maintained at all times. This activity is performed in accordance with the requirements of procedure BSC/PATH/SOP/047 titled “**Household Cleaning in the Pathology Department**” .
- Storage and disposal of dangerous materials is performed in compliance with current statutory regulations and provisions.

5.3 LABORATORY EQUIPMENT

5.3.1

- As described in 4.2.5 Laboratory Management are committed to ensuring procedures and programmes for proper calibration and functions of instruments, reagents and analytical systems. Laboratory Management ensure that the necessary resources are available through capital and material budgetary submissions. Only equipment fit for its intended purpose is used by the Pathology Department including equipment used for point of care testing.
- The scope of accreditation with respect to equipment is specific to that used at the permanent site. Refer to section 4.1.1 of this document.



5.3.2 Validation of Equipment

- Before new equipment is put into routine use, it must have demonstrated its performance capability with respect to stated user requirements.
- It is the policy of the Bon Secours Pathology Department that critical materials under go a document check before being put to routine use. Refer to section 4.6.2 of this document.
- Equipment facility or processes are validated as per the requirements of:-
 - Procedure BSC/QA/SOP/056 titled “**Procedure for Validation of Equipment or Facility**”. Equipment is shown to function as required during routine use. This functioning is demonstrated by the use of quality control samples and demonstrating proficiency by passing the relevant third party assessment schemes as appropriate.

Equipment Calibration/ Maintenance

- Laboratory Management have established and maintain documented procedures to control, calibrate and maintain all inspection measuring and test equipment so as to demonstrate the proper functioning of the equipment relevant to specified requirements. The Heads of Department, Laboratory Quality Assurance Officer and Validation Technician are responsible for the calibration activity. Refer to procedure BSC/QA/SOP/042 titled “**Control of Inspection, Measuring and Test Equipment**”.
- The following variable parameters are controlled using traceable test equipment:-
 - Sample volumes using scales or balances.
 - Sample volumes using pipettes or automated dispensers.
 - Sample temperature using thermometers or probes.
 - Environmental temperature using thermometers or probes.
 - Centrifugation speed using tachometer or strobe.
 - Time requirements for in process testing using stop watches.
- The following methods are employed to verify calibration:-
 - A master list of equipment is maintained by equipment group e.g. master list of scales/balances.
 - The dates calibrated equipment was issued and withdrawn are documented using the Asset Register.
 - The master list/ procedure or software controlling the calibration activity will identify:-
 - Precise equipment name
 - Location of equipment
 - Serial numbers and any other identifying tags, marks etc
 - Description of routine use of the equipment
 - The calibration requirements specification (accuracy/ precision) the equipment should meet
 - Frequency of calibration checks
 - Allowable error for test equipment
 - The type/ class of calibration equipment to be used
 - The test or functional requirement e.g. $37 \pm 2^{\circ}\text{C}$
 - All equipment used to calibrate measuring equipment must be certified and traceable to a primary standard
 - The primary standard will be calibrated at appropriate intervals



Note: The term "Primary Standard" refers to our master in house standard which is traceable to national and international primary standards.

- Non-conforming equipment is identified and labelled. Decontamination procedures as appropriate are performed prior to any service or maintenance being performed by Pathology personnel.
- A preventative maintenance programme is in place for equipment used for test and inspectional purposes. The preventative maintenance programme at a minimum follows the manufacturers recommendations as set out in the relevant equipment manual.

5.3.3 Each item of equipment is uniquely labelled (Asset Number) as per the requirements of document BSC/QA/URS/001 titled **“User Specification for the Set up and Use of a Database for the Entry, Modification and Management of an Asset Register for Equipment and Facilities Associated with the Pathology Department”**.

5.3.4 - The following records are maintained for each item or similar piece of equipment used for testing purposes.

Record ID	Record Description	Record Location
a.	Identity of equipment	Asset ID label is located on each piece of equipment. This record is also maintained on the Hospital Asset Management System (HAMS).
b.	Manufacturer’s name, equipment type, make, model and serial number.	This record is maintained on HAMS.
c.	Manufacturer’s contact person and telephone number.	This record is maintained on HAMS.
d.	Date of receipt and putting into service.	This record is maintained in the equipment file/ HAMS.
e.	Current location.	This record is maintained on HAMS.
f.	Conditions when received e.g. new, used or reconditioned.	This record is maintained in the equipment file.
g.	Manufacturer’s instructions/ manual	This record is maintained in the equipment file or at the point of use whichever is appropriate..
h.	Equipment performance records	Validation of equipment – Equipment file Calibration of equipment – Equipment file QC – On equipment/ floppy/ hardcopy EQA – EQA file (hardcopy)
i.	Maintenance carried out and planned for the future	PM records – Equipment file
j.	Damage, malfunction, modification and repair	These records are maintained in the equipment file.
k.	Predicted replacement date	Replacement date requirements are identified in the current capital budget submission for major items.



- The above equipment records are maintained as per BSC/QA/SOP/009 titled **“Procedure for the Control of Archive Documentation, Specimens and Preparations”**.

5.3.5 Only trained personnel operate critical equipment. Personnel have available (at the point of use) the relevant standard operation procedures and user manuals to operate and maintain the equipment.

5.3.6 Standard operating procedures and or user manuals define the safety precautions to be adhered to when using equipment.

5.3.7 - When equipment (including point of care) is found to be defective, it is taken out of service, clearly labelled **“DO NOT USE”** and appropriately stored until it has been shown by calibration, quality control material or otherwise to be functional. Records of such events are maintained in the equipment file.

- Such events are documented as non conformances as per the requirements of procedure BSC/QA/SOP/026 titled **“Control of Service/ System Non Conformance”**. In such instances corrective action requires a review to verify the validity of results traceable to the equipment in question.

5.3.8 - Prior to contracted person(s) working on equipment, as per breakdown or contractual agreement, such person(s) are instructed by Heads of Department/ nominee on:-

- Electrical safety
- Biological material safety

- External personnel are provided with the required protective equipment including clothing as appropriate.

- Refer to procedure BSC/PATH/SOP/019 titled **“Safety Requirements for External Contract Staff”**.

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

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

5.3.10 Where repair and maintenance require the equipment to be moved from its working location then prior to its return to routine use the equipment must be recalibrated (if appropriate).

5.3.11 Automated Systems

- The Laboratory Information System is interfaced with several automated testing processes. The Laboratory Information System controls the release of test reports as well as managing, in part, the traceability of blood components. The Laboratory software application (GAMP Category 4 software) is managed by the Laboratory Information Systems Manager who reports to the Laboratory Services Manager. The Laboratory Information System Manager with the Heads of Department and Laboratory Quality Assurance Officer ensure that:-



- a) Computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility.
 - b) Procedures are established and implemented for protecting the integrity of data at all times.
 - c) Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data.
 - d) Computer programmes and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorised persons.
- The use and control of the Laboratory Information System is described in:-
- Attachment 6.3 of this document titled “**Laboratory Information System (L.I.S.) Misys Current Version**”.
 - Section 5.1.7 of this document.
 - Annex B of ISO 15189: 2003E titled “**Recommendations for Protection of Laboratory Information Systems (LIS)**”.

5.3.12 The Laboratory has procedures for the safe handling, transport, storage and use of equipment to prevent contamination or deterioration. Refer to procedure BSC/QA/SOP/040 titled “**Procedure for the Control of Pathology Equipment including Service Contracts**”.

5.3.13 Where test calibrations give rise to a set of correction factors then procedures are in place to ensure that prior correction factors are correctly updated.

5.3.14 Access to and use of areas affecting the quality of examinations is controlled. Security measures are in place to safe guard resources (material, equipment, personnel, software and hardware) from unauthorised access. Key pad access control is in place. Refer to procedure BSC/PATH/SOP/040 titled “**Security**”.

5.4 PRE-EXAMINATION PROCEDURES

- 5.4.1** - The Laboratory has a number of test request forms controlling the ordering of Laboratory tests. For details of the request forms used, refer to the “**Primary Sample Collection Manual**” document BSC/PATH/GDE/001 and section 4.4.1 of this document. Request forms used are required to contain the following **essential** information in a **legible** manner:-
- a) **Unique identification** of the patient
 - Forename and surname
 - Date of birth
 - Hospital number
 - b) **Name and address** of the physician requesting the test.
The address is required where the location of the physician is external to that of the Bon Secours Hospital, Cork.
 - c) **Type of primary samples** (i.e. blood, urine, stool) and anatomical site of origin (where appropriate).
 - d) The **examination tests** requested.
 - e) **Clinical information** relevant to the patient which should include **date of birth** and **gender** as a minimum for interpretation purposes.
 - f) **Date and time** of primary sample collection.



- g) **Date/ time of receipt** of primary samples into the laboratory.
- h) A clear indication as to whether the tests requested are **urgent** or **routine**.

- The Laboratory Services Manager ensures where **new forms or amendments** to existing forms are required that prior to implementation any such changes are discussed and agreed with the relevant clinical users.
- For use of non prescribed request forms, refer to section 4.4.1 of this document.

5.4.2 An approved Primary Sample Collection Manual, which records specific instructions for the proper collection and handling of primary samples is circulated to the primary users of the Laboratory services. The Primary Sample Collection Manual is circulated to:-

- Phlebotomy
- Pathology Office
- Specimen Reception
- The Assistant Director of Nursing

For internal users an **electronic version** of the manual is stored on the desktop under an icon titled **Public Documents/ Pathology Documents**. The document is stored in Adobe Acrobat format, which allows all computer users to read the document while preventing modification. Instructions on how to use the electronic version of the manual have been issued to Clinical Nurse Managers who have posted laminated instructions at workstations. It is the responsibility of Clinical Nurse Managers to ensure that all staff are familiar with accessing the document. For external users an electronic version of the manual is available on the Bon Secours Website www.bonsecoursireland.org.

5.4.3 The **Primary Sample Collection Manual** includes the following:-

a) Reference to or including:-

1. A **list** of available Laboratory tests/ examinations offered.
2. A reference to tests/ examinations requiring completion of **consent** form (under the heading special requirements).
3. A reference to the required instructions provided to patients by the primary health carer in relation to the **patient's own preparation** before primary sample collection.
4. **Information for users** of Laboratory services on medical indications and appropriate selection of available procedures. The Pathology department welcomes queries or requests for advice. Section 3.2 of the Primary Sample Collection Manual lists contact telephone numbers for the relevant medical and scientific personnel.

b) Procedures for:-

1. **Preparation of the patient.** The procedures for preparation of the patient prior to primary sample collection are defined or referred to in the **Primary Sample Collection Manual** and Phlebotomy procedures. Refer to:-
 - BSC/PHLE/SOP/001 titled "**Procedure Venepunction of Inpatients by Phlebotomy Staff**"
 - BSC/PHLE/SOP/003 titled "**Procedure Venepunction of Outpatients by Phlebotomy Staff**"
 - The Primary Sample Collection Manual under heading "Special Requirements".



The Primary Sample Collection Manual does not define instructions for the preparation of the patient in the case of dynamic tests. This is the responsibility of the Hospital clinician.

2. **Identification of Primary Sample.** Refer to:-

- Section 4.2 of the Primary Sample Collection Manual titled “Completing the Request Form”.
- Section 13.3 of the Primary Sample Collection Manual titled “Special Requirements for Microbiology Sampling and Testing”.
- Sections 9 to 14 of the Primary Sample Collection Manual where for each stated test the primary sample type is identified.

3. **Primary Sample Collection.**

For each stated test, the Primary Sample Collection Manual sections 9 to 14 describe the **container and additive** to be used for primary sample collection.

c) **Instructions for:-**

ID	Instructions For	Primary Sample Collection Manual Reference
1.	Completion of the request form.	Section 4.2 titled “Completing the Request Form” of the Primary Sample Collection Manual
2.	Type and amount of primary sample to be collected	Sections 9 to 14 of the Primary Sample Collection Manual
3.	Special timing of collection	Special requirements column of section 9 to 14 of the Primary Sample Collection Manual
4.	Specimen handling requirements	Special requirements column of section 9 to 14 and section 5.0 titled “Delivery, Packing, Transport and Postal Requirements for Diagnostic and Infectious (or Suspected Infectious) Specimens” of the Primary Sample Collection Manual
5.	Labelling of primary samples	Section 4.3 titled “Labelling the Specimen Container” of the Primary Sample Collection Manual
6.	Clinical information	Section 4.2.1 (11) of the Primary Sample Collection Manual
7.	Positive identification of the patient prior to sample collection	Refer to the Phlebotomy procedures - BSC/PHLE/SOP/001 titled “ Procedure Venepunction of Inpatients by Phlebotomy Staff ” - BSC/PHLE/SOP/003 titled “ Procedure Venepunction of Outpatients by Phlebotomy Staff ” and JCI policy NUR/11 titled "Patient Identification".
8.	Recording the name of personnel collecting the specimen	Section 4.3.1 titled “Completing the Request Form” of the Primary Sample Collection Manual
9.	Safe disposal of materials used in the primary sample collection	Section 5.4 titled “Disposal of Waste Material Used in Specimen Collection” of the Primary Sample Collection Manual.



d) Instructions for :-

ID	Instruction Description	Primary Sample Collection Manual Reference
1.	Storage of examined samples	Section 5.5 titled “Storage of Examined Samples for Archive or Look Back Purposes” of the Primary Sample Collection Manual.
2.	Time limits for requesting additional examinations	The time limits for requesting additional examination are not defined as each request is reviewed on a case by case basis by Laboratory personnel.
3.	Additional examinations	Section 8.3.2 titled “Further Examination of the Primary Specimen” of the Primary Sample Collection Manual
4.	Repeat examination due to analytical failure or further examination of primary sample	Section 8.3.1 titled “Repeat Examination due to Analytical Failure” of the Primary Sample Collection Manual

5.4.4 The Primary Sample Collection Manual is a controlled document and is issued and circulated per the requirements of procedure BSC/QA/SOP/005 titled “**Operation of a Controlled Document System**”.

- 5.4.5**
- Primary samples and associated forms are checked on receipt by the Specimen Reception Laboratory. Where the specific requirements of the incoming inspection process for samples and forms are not met for key indicators, then the requesting of a second specimen or other defined actions are undertaken. Refer to BSC/PATH/SOP/030 titled “**Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens**”.
 - In cases where there is **uncertainty in the identification** or the **validity** of the primary samples or **stability** of the analytes and the primary specimen is irreplaceable or critical then such specimens may be accepted but only if the originator documents their acceptance of the primary sample by their signature on the request form or other relevant document. The final report records the non conformance and also indicates the name of the person who accepts responsibility for the sample in cases where formal acceptance of the primary sample was not possible or practical.
 - All non conforming primary samples (even when tests are not performed) **must be registered** on the Laboratory Information System. The electronic registration will identify the reason for rejecting the samples and the action taken e.g. second specimen requested.



5.4.6 Transport of Primary Samples

Specimens from ward locations are transported to the Laboratory via a pneumatic tube system, refer to procedure BSC/PATH/SOP/029 titled "Procedure for the Use of the Pneumatic Tube System (PTS)". The Laboratory monitors and ensures by appropriate means that samples are transported to the Pathology department in such a way that the validity of the test results are not compromised. This is accomplished by the following:-

- a) The Primary Sample Collection Manual clearly identifies any **special time related** requirements associated with specific tests to the user. Before testing the Laboratory verifies these requirements are complied with.
 - b) The Primary Sample Collection Manual, under the special requirements section, clearly identifies any **specific temperature requirements** associated with preserving the integrity of specific test parameters. Before testing the Laboratory verifies these requirements are complied with.
 - c) Adherence to regulations controlling transport of specimens. Refer to **“The European Agreement Concerning The International Carriage Of Dangerous Goods by Road (UNADR)”**.
- The Primary Sample Collection Manual defines for the users of Laboratory services:-
- Requirements for specimen delivery from within the Hospital. Refer to section 5.2 of the Primary Sample Collection Manual.
 - Requirements for specimen delivery from outside the Hospital. Refer to section 5.3 of the Primary Sample Collection Manual.

5.4.7 All samples received into the Laboratory either during routine or out of hours **are recorded electronically** on the Laboratory Information System. The electronic receipt of specimens controls the following:-

- Date/ time of receipt of samples
- The tests requested and any non conforming events
- Audit trail (including who received the specimen)

5.4.8 - Procedures are in place for the acceptance and rejection of primary samples. The acceptance or rejection is based on an inspection process, where each specimen is reviewed for compliance with defined criteria as it applies to:-

- Suitability of the request form
- Labelling of the primary samples
- Quality of the specimens (age, haemolysis, lipaemia, volume etc)

- A log of non conforming specimen/ form issues is retained and reviewed. The findings are reviewed by:-

- The Monthly Quality Assurance meeting
- The Monthly Hospital Best Practice meeting. Refer to section 4.4 of this document.

- Quality improvement processes are identified to reduce the number of reported specimen/ form issues.

- This activity is controlled by procedure BSC/PATH/SOP/030 titled **“Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens”**.



- 5.4.9** The Laboratory formally reviews its sample volume requirements for Phlebotomy to ensure neither sufficient but not excessive amounts of primary samples are collected. This review takes place at intervals no longer than 2 years as per controlled document review requirements. Refer to procedure BSC/QA/SOP/005 titled “**Operation of a Controlled Document System**”. The primary sample **volume** requirements are defined in document BSC/PATH/GDE/001 titled “**Primary Sample Collection Manual**”.
- 5.4.10** This clause is **not applicable** as the registration process assigns bar-coded labels, in built into which are the defined test methods. The registration process interfaces bi-directionally with automated equipment.
- 5.4.11** **Urgent Specimens**
The Laboratory (Specimen Reception department) has documented procedures in place for the receipt, labelling, processing and reporting of primary samples received by the Laboratory and are **marked as urgent**. This activity is controlled by the following procedures:-
- BSC/PATH/SOP/030 titled “**Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens**”.
 - BSC/PATH/SOP/060 titled “**Procedure for the Review and Release of Reports to Users**”.
- 5.4.12** Sample portions or aliquots are labelled so that they are traceable to the original primary sample. Refer to procedure BSC/PATH/SOP/030 titled “**Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens**”.
- 5.4.13**
- It is the policy of the Pathology department to accept requests for additional tests (verbally) using the same accession number. Ideally, a request form should accompany such a request but the lack of the request form will not impede the processing of an urgent request.
 - During routine hours the Specimen Reception department and out of hours on-call staff:-
 - Accept or reject the request for additional tests based on review of the specimen(s) for adequacy (specimen size, age, etc). Refer to procedure BSC/PATH/SOP/030 “**Procedure for the Receipt, Checking, Computer Registration, Secondary Processing Including Labelling and Distribution of Pathological Specimens**”.
- 5.4.14** After the results have been reported, primary samples are stored for a specified time under conditions (only applies to certain specimen types), which ensures stability of sample properties which enables the sample to be repeated or additional examinations to be requested after reported. Refer to procedure BSC/QA/SOP/009 titled “**Procedure for the Control of Archive Documentation, Specimens and Preparations**”.



5.5 EXAMINATION PROCEDURES

5.5.1 The Pathology Department uses examination procedures (testing) which meet the needs of its users. The Pathology Department uses examination procedures (testing) that are in wide spread use and have been published or referenced in authoritative textbooks and journals. This includes point of care tests.

- 5.5.2**
- Testing procedures including point of care or amended procedures are validated or verified by the Laboratory prior to being introduced into routine use. The Laboratory records the results of validations and the procedures used for such validation.
 - Validations are performed in accordance with the requirements of procedure BSC/QA/SOP/058 titled “**Procedure for the Validation of Test Methods**”.
 - A **validation file** is retained and maintained for test method including point of care testing or group of parameters that constitute the method e.g. Full Blood Count. The validation file contains the following:-
 - Method Change Control Log
 - Plan for verification of the test method
 - Test method verification data and approvals
 - Laboratory Information System (Sunquest) forms and documentation:-
 - Copy of Laboratory Information System (LIS)/ test battery change form
 - Copy of new code request form
 - LIS Maintenance inquiry reports including calculations (if appropriate) and English text appended to result
 - Sample report printouts : cumulative and client to verify stated reference intervals in the maintenance inquiry report
 - Support documentation for reference intervals
 - Method Summary Report Sheet
 - Uncertainty of Measurement
 - On Going Review of Reference Ranges
 - Ongoing Test Verification Plan
 - Manufacturer’s Product Insert/ Method Sheet (current version)
 - Relevant updates from the manufacturer of the Test Kits or Equipment
 - Correspondence to Wards/ Clinicians relevant to the test method (notification of change)
 - Note: Validation
 - The manufacturers of kits have fully validated the test methods i.e. it has been proven in their hands, using stated equipment, materials and procedures that the test method provides consistent reliable results and has been delivered by a quality approved company.
 - Prior to using new or amended methods, the Laboratory verifies that results are at least comparable with the manufacturer’s expectations for stated performance specifications and a comparative method.
 - Validation or verification of existing “proven” methods is based on verification of accuracy (fixed/ variable result methodologies) and precision (for variable result methodologies).



- 5.5.3**
- Standard Operating Procedures are available at work stations where test and examination procedures are performed. This includes point of care tests. To supplement the procedures, process flow documentation (controlled) is available at appropriate work stations. The process flows are considered an excellent method of inducting new staff, explaining the process to visitors, as an aid in problem solving and informing clinicians and external auditors of the process. Refer to procedure BSC/QA/SOP/022 titled “**Functional Process Flow Charts**”.
 - The test method procedures are based in whole or as part of the method sheet or product insert or other instructions provided by the manufacturer. Each Laboratory or relevant section has folders of method sheets/ product inserts (current versions). As part of the incoming inspection process, the method sheets/ insert kits are checked for current version. All proposed changes are controlled by procedure BSC/QA/SOP/054 titled “**Procedure for the Control of Change to Equipment, Processes, Techniques and Controlled Documentation**”.
 - The validation file contains the following information on the test method:-
 - a) Purpose of the examination
 - b) Principle of the procedure used for examinations
 - c) Performance specifications (e.g. linearity, precision, accuracy, reportable interval, sensitivity and specificity)
 - d) Primary sample system (e.g. plasma, serum, urine)
 - e) Type of container
 - f) Required equipment and reagents
 - g) Calibration procedures (metrological traceability)
 - h) Procedural steps
 - i) Quality control procedures
 - j) Interferences (e.g. lipaemia, haemolysis, bilirubinaemia) and cross reactions
 - k) Principle of procedure for calculating results, including measurement uncertainty
 - l) Biological reference intervals
 - m) Reportable interval of patient examination results
 - n) Alert/ critical values, where appropriate
 - o) Laboratory interpretation
 - p) Safety precautions
 - q) Potential sources of variability
 - r) Participation in third party assessment schemes
- 5.5.4**
- Performance specifications are in place for all methods and are relevant to the intended use of that procedure. Not all performance specifications are applicable to all methods.
 - Performance specifications include and are defined as follows:-
 - a) **Linearity**
The highest quantity of an analyte that can be measured by a test method without dilution.
 - b) **Precision**
Is a measure of how close each of the measured values are to each other. A measurement may be imprecise due to random errors.



- c) **Accuracy**
Is a measure of how close the measured value is to the target or nominal value. A measurement may be inaccurate due to a constant bias.
- d) **Sensitivity**
The least quantity of an analyte that can be measured by a test method (limit of detection).
- e) **Reportable Interval**
Is the range as defined by the limit of detection and linearity measurements.
- f) **Specificity**
The degree to which a test method is subject to interference from other analytes.
- g) **Alert/ Critical Values**
Is the value that is considered to be so abnormal that action must be taken by the Laboratory (e.g. phone results) so that clinical intervention can take place or be considered.
- h) **Reference Intervals**
The distribution of an analyte in a **specific population** expressed at the 95% confidence limits (± 2 SD) or other appropriate range as clinically defined.

- 5.5.5 - Biological reference intervals are periodically reviewed with respect to:-
- Appropriateness to the population being served.
 - Changes in examination procedures
 - Changes in pre examination procedures
- Biological reference intervals as stated in controlled documentation must be reviewed ≤ 2 years as per the requirements of procedures BSC/QA/SOP/005 titled "**Operation of a Controlled Document System**" and BSC/QA/SOP/058 titled "**Procedure for the Validation of Test Methods**".

5.5.6 The Pathology Department (medical consultant or nominee of same) provides details of current examination procedures including performance specifications etc. to clinical users on receipt of request for same.

5.5.7 It is the policy of the Pathology department that the relevant Laboratory Medical Consultants/ nominees inform clinical users in advance of change to an examination procedure, where the change has an impact on interpretation (i.e. change in reference internal or other performance specifications). The notification should be in writing and can be by hardcopy or electronic methods. Records of each notification are maintained with the validation file. This notification policy includes point of care tests.



5.6 ENSURING QUALITY OF EXAMINATION PROCEDURES

- 5.6.1** - The quality of examination results including point of care tests is **assured** with reference to the following:-
- A comprehensive quality control approach to pre-testing, testing and post testing processes. The approach to quality control is based on principles of in-process QC checks. As well as controlling the tests the key inputs to each process will be reviewed and signed off on a daily basis.
 - It is the policy of the Laboratory to focus on elimination or reduction of errors in the following critical areas of activity:-
 - Specimen Collection, inspection and registration. Refer to section 5.4 of this document.
 - Laboratory Information System including interfaces and data entry contingency. Refer to section 5.2 and 5.3 of this document.
 - Primary processing including centrifugation and aliquoting. Refer to section 5.4 of this document.
 - Testing processes (using QC samples).
 - Reports. Refer to section 5.8 of this document.
 - All known errors in the internal QC systems are documented as per the requirements of procedure BSC/QA/SOP/026 titled “**Control of Service System Non Conformance**”.

Refer to procedure BSC/QA/SOP/024 titled “**Performance and Review of Internal Quality Control and External Quality Assessment Samples**”.

- 5.6.2** Uncertainty of measurement is determined where it is **relevant** and **required** in the interpretation of the result. Refer to procedure BSC/QA/SOP/059 titled “**Determination of Uncertainty of Measurement**”.

- 5.6.3** - To verify the correctness of results, equipment calibration programs are in place for measuring systems. The scope and type of calibration programs are defined by procedure. Refer to procedure BSC/QA/SOP/042 titled “**Control of Inspection, Measuring and Test Equipment**” and section 5.3.2 of this manual.
- Where it is not possible, relevant or where other confirmation is required to verify the correctness of a result other than by equipment calibration method then the Laboratory may use other methods to provide confidence in the results:-
- a) Participation in all available and suitable inter Laboratory comparison programs e.g. NEQAS programs. Refer to procedure BSC/QA/SOP/024 titled “**Performance and Review of Internal Quality Control and External Quality Assessment Samples**”.
 - b) Using reference materials which are certified to indicate the characterisation of the material e.g. A.T.C.C. (American Type Culture Collection) control organisms.
 - c) Examination or calibration by another procedure e.g. osmolality controls.
 - d) Ratio or reciprocity type measurements.
 - e) Methods which are clearly established, specified, characterised and mutually agreed by the Laboratory and the clinical user e.g. the HbA_{1c} method is IFCC (Diabetes Control and Complication Trial) aligned.
 - f) Use of certificates of analysis or conformance provided by manufacturers or agents of same as a method of verifying reagent, test procedures or analytical systems.



- Our system of control is based on the summation of the individual components as defined above.

- 5.6.4**
- Our testing Laboratories (including point of care testing), participate in all available third party external assessment schemes.
 - The Head of Department/ relevant Laboratory Medical Consultant formally reviews the results of external assessment schemes. The output of this review is presented at the Monthly Quality Assurance meeting. Each Head of Department presents an overview of performance at the Annual Management Review meeting. Refer to section 4.15.2 of this document. Data from point of care EQA schemes is reviewed at the quarterly point of care committee meetings.
 - Failures in external quality assessment schemes and internal quality control methods are documented and investigated in accordance with the requirements of procedure BSC/QA/SOP/026 titled **“Control of Service System Non Conformance”**.
 - It is the policy of the Laboratory and the responsibility of each Head of Department to ensure that external quality assessment specimens, in so far as possible, are treated as routine specimens. External quality assessment samples go through the normal registration, pre examination and post examination process.
 - External assessment samples are used to check the competency of staff as per the requirements of procedure BSC/QA/SOP/018 titled **“Pathology Proficiency Testing of Laboratory Staff to Ensure Competency”**

5.6.5 Where formal external quality assessment schemes are not available, are inadequate or do not challenge the full range of the analyte, the Laboratory may use external derived primary samples or portions of same to verify the test method. The review of the results and any associated corrective actions of such interlaboratory comparison are performed in accordance with 5.6.4.

5.6.6 It is the policy of the Laboratory to seek accreditation only for those tests that:-

- Are performed on the permanent site, refer to section 4.1.1 of this document.
- Have an adequate internal Quality System in place.
- Have third party assessment schemes in place.

5.6.7 The relevant Head of Department or nominee is responsible for monitoring and updating records traceable to third party assessment schemes. These records include the documented actions, reports and non conformances.

5.7 POST EXAMINATION PROCEDURES

5.7.1 Only authorised personnel (Trained Personnel) review, evaluate and authorise the release of results. This activity is controlled by procedure BSC/PATH/SOP/060 titled **“Procedure For The Review And Release Of Reports To Users”**.

5.7.2 After testing, primary samples and portions of samples are stored in accordance with the requirements of procedure BSC/QA/SOP/009 titled **“Procedure for the Control of Archive Documentation, Specimens and Preparations”**.



- 5.7.3** Primary samples, portions of samples and material used in the testing process but no longer required, are disposed of safely in accordance with the requirements of :-
- Guidelines for waste management (hospital policy document).
 - Procedure BSC/PATH/SOP/009 titled “**Segregation And Disposal Of Waste (Including Bio Hazard Material) From The Pathology Department**”.

5.8 REPORTING OF RESULTS

- 5.8.1**
- The Laboratory Director (Laboratory Services Manager and Clinical Director) are responsible for approving the format of Laboratory test reports. The format review process is cognisant of the view and opinions of the Hospital Consultants and other users of the Laboratory services.
 - The reports (hard copy) are of a standard format which has been approved by the Laboratory Director.
 - Hospital based users have electronic access to view results on the Hospital Information System (HIS) as soon as the results are released. Hardcopies of the report are issued on the day of test report release. Hardcopy reports are issued to:-
 - The ward for the patient’s file
 - The Consultant, Clinician or external practitioner e.g. GP as appropriate.
 - Hardcopies of the reports are issued at the next scheduled print run, usually on the same day. Individual reports may be issued at the discretion of the Consultant Pathologist.
 - Reports (hardcopies) may be printed directly from the HIS by a limited number of authorised users. The Consultant Pathologist and Laboratory Services Manager must authorise the access to printing from HIS. These printed reports do not form part of the patient's medical file.
- 5.8.2** Laboratory Management and the requestor shares responsibility for ensuring that the reports are available for review/ interpretation by a responsible person in a timeframe that complies with agreed arrangements. These agreed agreements are defined in document BSC/PATH/GDE/001 titled “**Primary Sample Collection Manual**”.
- 5.8.3** Reports printed are legible and reviewed for mistakes at authorisation stage particularly where there is transcription involved (e.g. use of Dictaphones). Reports are issued to authorised personnel and/ or locations as defined in section 5.8.1 of this document. Reports are formulated to include the following:-
- a) Clear identification of the test(s)
 - b) Identification of the Laboratory (Bon Secours Hospital, College Road, Cork)
 - c) Patient’s full name, date of birth, home address and destination of report (internal or external).
 - d) Name of the requestor i.e. person to receive the report and the address of the requestor if external to the Hospital.
 - e) Date/ time of primary sample collection and receipt where the Laboratory date only applies to Histopathology reports.
 - f) Date and time report was released. For non Histopathology reports, the date and time of releasing is not recorded on the report. However, all time release transactions are recorded electronically and are available for review on the LIS transaction log.



- g) Primary sample type and anatomical site of origin.
- h) Results of the examination reported in SI units or units traceable to SI units as applicable. Refer to ISO Guide 31.
- i) Biological reference intervals where applicable.
- j) Interpretation of results (specific to Histopathological reports).
- k) Free text or predefined Laboratory comments to comment on the adequacy of primary sample or other factors which may have impacted on the trueness of the result.
- l) Identification of the person who authorised the release of the report. For non Histopathology reports, the date and time of authorisation is not recorded on the report. However, all authorisation transactions including name are recorded electronically and are available for review on the LIS transaction log.
- m) Original and corrected results.
- n) There is no signature or mark signifying who checked or released the report. This process is performed electronically and all transactions are available for review on the LIS transaction log.

Note 1: The name and location of the referral laboratory is identified with the test result issued by the Pathology Department (Bon Secours).

Note 2: For point of care tests, the results must be recorded in the patient file (Medical Record). The identity of the person performing the point of care test should be recorded.

- 5.8.4** - The examinations (tests) performed follow the **vocabulary** and **syntax** recommended by:-
- International Council for Standardisation in Haematology (**ICHS**)
 - International Federation of Clinical Chemistry and Laboratory Medicine (**IFCC**)
- The **description** of results follows the nomenclature recommended by the World Health Organisation (**WHO**).

5.8.5 The report identifies using free text or predefined Laboratory comments a statement on the adequacy of primary sample or other factors which may have impacted on the trueness of the result e.g. haemolysis, lipaemia.

5.8.6 Copies of reported results are retained electronically on the Laboratory Information System (LIS). This ensures prompt retrieval of the information. The master copy of the report is assigned to the patient file and is controlled by the Medical Records department. The electronic and hardcopy records are maintained permanently as per the requirements of BSC/QA/SOP/009 titled “**Procedure for the Control of Archive Documentation, Specimens and Preparations**”.

Note: Point of care results must be distinguishable from results released in the Laboratory.

5.8.7 The Laboratory has procedures in place, refer to procedure BSC/PATH/SOP/060 titled “**Procedure for the Review and Release of Reports to Users**” for immediate notification of clinical personnel when examination results for critical properties or parameters fall within documented alert/ critical values, refer to section 5.5 of this document. The Laboratory Medical Consultants have authorised lists of analytes/ parameters and their associated alert/ critical values.

5.8.8 The alert/ critical values have been drawn up in agreement with the users of the Laboratory services.



- 5.8.9** Where results are transmitted as an interim report, a final report is always issued to the requestor.
- 5.8.10** In response to results achieving the defined alert/ critical values, Laboratory personnel communicate with relevant clinical personnel and the record of this communication shows the following details:-
- Date and time of communication
 - Identity of the Laboratory staff member
 - Identity of the person notified
 - The examination results and any other comment relevant to the communication
- 5.8.11** - Turnaround time for test requested by users are identified in BSC/PATH/GDE/001 titled **“Primary Sample Collection Manual”**.
- The turnaround times are monitored, recorded and reviewed as per procedure BSC/PATH/SOP/062 titled **“Management and Review of Test/ Process Turnaround Time”** on a monthly basis. The review process feeds into the annual Quality Management Review process. Refer to procedure BSC/QA/SOP/020 titled **“Procedure for Quality Management Review”**.
- Where results are delayed, for whatever reason, then such events will be documented as non conformances as per the requirements of procedure BSC/QA/SOP/026 titled **“Control of Service System Non Conformances”**. Corrective action in such cases should include communicating the reason for delay with the requestor of the test.
- 5.8.12** It is the policy of the Pathology Department not to refer tests within the scope of accreditation to external laboratories. Refer to section 4.5.1 of this document.
- 5.8.13** The Laboratory has a documented procedure for the release of examination results including details of who may release results and to whom. This procedure also includes guidelines for the release of results directly to patients. Refer to procedure BSC/PATH/SOP/060 titled **“Procedure for the Review and Release of Reports to Users”**.
- 5.8.14** It is the policy of the Pathology department to telephone reports only when results for specific clinical parameters have reached critical levels or where requests are made for verbal reports in urgent cases. The Laboratory has a procedure for ensuring that reports provided verbally are followed by a formal hardcopy report. Laboratory personnel record details of the communication with the relevant clinical personnel and this record will show the following details:-
- Date and time of communication
 - Identity of the Laboratory staff member
 - Identity of the person notified
 - The examination results and any other comment relevant to the communication
- The examination results and any other comment relevant to the communication. Refer to procedure BSC/PATH/SOP/060 titled **“Procedure for the Review and Release of Reports to Users”**.



- 5.8.15** Procedure requires alterations to reports to be documented on the hardcopy of the report i.e. the old and modified versions of the report remain legible on the report. The Laboratory Information System (LIS) transaction log defines the time, date and name of person responsible for the change.
- 5.8.16** The Laboratory Information System (LIS) maintains and can issue a cumulative report including those reports that have been revised. These reports are available to relevant clinical decision-making personnel.

6.0 ATTACHMENTS

- 6.1** Document titled “Organisational Charts (Pathology/ Blood Transfusion/ Point of Care Testing)”
- 6.2** Document titled “The Quality Policy of the Pathology Department, Bon Secours Hospital, Cork”
- 6.3** Document titled “Laboratory Information System (L.I.S.) Sunquest (Misys) Current Version”