

<b>QMn-GEN-0001</b> <b>Rev. No. 18</b>	<b>Quality Manual</b>	<b>Page 1 of 82</b> <b>Effective Date:</b> <b>29/01/2019</b>
<b>Author: Kathleen Callan</b>		<b>Authoriser: Dr Su Maung</b>



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

# QUALITY MANUAL

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Author: Kathleen Callan		Authoriser: Dr Su Maung

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## **1. INTRODUCTION**

### **1.1 Purpose**

- 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 Department of Pathology, Our Lady's Hospital, Navan. This document forms the organisations response/approach to the requirements of the following regulations and standards:
- *ED-BB-0141* Blood Directive – Directive 2002/98/EC - Setting the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood products and amending Directive 2001/83/EC.
- *ED-BB-0002* SI 360 / 05 - European Communities (Quality and Safety of Human Blood and Blood Products) Regulations 2005. This is the statutory instrument which adapts the EU Directives as defined above Into Irish law.
- *ED-BB-0161* Traceability SI 547/06 - Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC.
- *ED-BB-0003* AML-BB current version; Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events ) of EU Blood Directive 2002/98/EU.
- *ED-BB-0001* Directive 2005/61/EC - Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.
- *ED-BB-0027* Directive 2005/62/EC- Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards community standards and specification relating to a quality system for blood establishments.
- *ED-GEN-0147* Directive 98/79/EC\_– In Vitro Medical Devices Directive.
- *ED-GEN-0148* SI No 304/2001 European Communities (In vitro Diagnostic Medical Devices) Regulations 2001
- *ED-GEN-0004* ISO 15189:2012(E) - International Standard ~ Medical Laboratories – Particular requirement for Quality and Competence.
- *ED-GEN-0137* HIQA May 2010 – National Standards for the Prevention and Control of Healthcare Associated Infections.
- *ED-GEN-0007* INAB Regulations, Terms and Conditions.
- *ED-GEN-0138* Infectious Diseases Regulations (Current version)
- *ED-GEN-0132* Ethics in Public Office Acts (Current version)

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- *ED-GEN-0134* Public Service Management (Recruitments and Appointments) Act (Current version)
- *ED-GEN-0131* Disciplinary Procedure for Employees of the Health Service Executive (Current version)

Health Products Regulatory Authority has been designated by the Department of Health and Children (DOHC) as the competent authority for overseeing the implementation of these regulations in all Hospital Blood Banks in Ireland.

## **1.2 Overview of Our Lady's Hospital**

### ***Governance Background***

Our Lady's Hospital, Navan is part of the **Ireland East Hospital Group (IEHG)**. This group also includes the Mater Misericordiae University Hospital, St Vincent's University Hospital, Midland Regional Hospital, Mullingar, St Luke's Hospital, Kilkenny, Wexford General Hospital, National Maternity Hospital, St Columcille's Hospital, St Michael's Hospital, Dun Laoghaire, Cappagh National Orthopaedic Hospital and the Royal Victoria Eye and Ear Hospital. The Academic Partner nominated is University College, Dublin.

The Laboratory Director is Dr Su Maung, Consultant Haematologist and also has responsibility for Haematology and Blood Bank (Blood Transfusion Laboratory & Haemovigilance)

Dr Emilia Manwa, Consultant Microbiologist has responsibility for Microbiology, Dr Michael Louw, Consultant Chemical Pathologist provides advisory services to Biochemistry. Mr Ray O'Hare is the Chief Medical Scientist.

### ***Capacity***

Our Lady's Hospital, Navan has a capacity of 136 beds.

### ***Services Provided***

Our Lady's Hospital, Navan provides a general acute hospital service to the catchment area of Meath and an orthopaedic service to the region as a whole. Services provided at the hospital are detailed in Table 1. *Services Provided at Our Lady's Hospital*

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**Table 1. Services Provided at Our Lady's Hospital, Navan**

General Medicine	Pathology
Emergency Medicine	Radiology
Orthopaedics	Physiotherapy
Gynaecology Day Surgery	Pharmacy
Palliative Care	Cardiology
General Surgery	Occupational Therapy

### **1.3 Overview of Department of Pathology**

The Department of Pathology provides a comprehensive service to Our Lady's Hospital, Navan. It includes:

- Blood Bank (Blood Transfusion Laboratory & Haemovigilance)
- Haematology
- Biochemistry
- Microbiology

Pathology Governance meetings are held on site every 2 months.

## **2. QUALITY MANAGEMENT SYSTEM**

The Quality Management System is produced to direct and control the Department of Pathology with regard to quality. The Department of Pathology Management Team consists of the Laboratory Director of the Department of Pathology, Laboratory Consultants (Consultant Haematologist, Dr Su Maung, clinical responsibility for Haematology and the Blood Bank, Dr Emilia Manwa, clinical responsibility for Microbiology and Dr Michael Louw, Consultant Chemical Pathologist clinical responsibility for Biochemistry, the hospital General Manager and the Chief Medical Scientist.

The Laboratory Director is Dr Su Maung, Consultant Haematologist.

Ray O'Hare the Chief Medical Scientist is responsible for the Day to day operations in the Laboratory including responsibility for Scientific and Administration Issues and he reports directly the General Manager.

Appendix 1 *QF-GEN-0060 Department of Pathology Organisational Chart* clearly defines the lines of communication and responsibility within each laboratory in the Pathology Department.

All personnel are required to follow these lines of communication and authority without exception.

## **3. TERMS AND CONDITIONS**

For the purpose of this document the terms and conditions will be taken from ISO 15189:2012

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## 4. MANAGEMENT REQUIREMENTS

### 4.1 Organisation and Management Responsibility

#### 4.1.1 Organisation

##### 4.1.1.1 General

The Department of Pathology is committed to performing its activities in accordance with the requirements of the International Standard ISO 15189 (current version). All work in the Department of Pathology relevant to the scope of ISO 15189 accreditation is carried out in the permanent facility.

The Department of Pathology consists of a Chief Medical Scientist, Senior Medical Scientists, Basic Medical Scientists, a Haemovigilance Officer, Phlebotomists, a Clerical Officer and Laboratory Aides. Medical Scientists participate on a voluntary basis on the multi-discipline on-call rotation which includes all departments.

The Blood Bank in Our Lady's Hospital, Navan has been accredited to ISO 15189 since 17<sup>th</sup> February 2009. The scope of the accreditation is detailed in Registration Number 215MT. All work relevant to the scope of ISO 15189 (current version) accreditation is carried out in the permanent facility.

*LF-BT-0111 Schedule of Testing for Blood Transfusion* includes a list of the tests that are included in the scope of ISO15189 accreditation for the Blood Bank in Our Lady's Hospital, Navan.

The Haematology and Biochemistry Departments have been accredited since 2016 following initial inspection in October 2015. *QF-HAEM-0004 Schedule of Testing for the Haematology Department* and *QF-BIO-0007 Schedule of Testing for the Biochemistry Department* include a list of the tests that are included in the scope of ISO15189 accreditation for Haematology and Biochemistry respectively.

Extension to scope for Microbiology was awarded in October 2018 following the initial inspection in April 2018. Ref.: *QF-MIC-0012 Schedule of Testing for Microbiology*.

##### 4.1.1.2 Legal Entity

The Department of Pathology in Our Lady's Hospital, Navan **is held legally responsible for its activities** within the Health Service Executive. The Department of Pathology of Our Lady's Hospital, Navan is situated on the first floor of the main hospital building.

**Address:** Department of Pathology,  
Our Lady's Hospital,

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Navan,  
Co. Meath.  
C15 RK7Y

<b>Telephone:</b>	Hospital Switchboard	046 9021210
	Laboratory Office	0469078701
	Blood Bank	046 9078573
	Haematology	0469078575
	Biochemistry	0469078574
<b>Fax:</b>	Laboratory Office	046 9098016

#### **4.1.1.3 Ethical Conduct**

All aspects of ethical conduct in the Department of Pathology, Our Lady's Hospital, Navan are managed in accordance with the ED-GEN-0132 *Ethics in Public Office Acts 1995 and 2012* MP-GEN-0026 *Code of Conduct for Laboratory Personnel & Confidentiality Statement*.

Laboratory management has arrangements in place to ensure the following:

- a) It is the Department of Pathology policy not to be involved in any activity that would diminish confidence in its competence, impartiality, judgement or operational integrity. This is achieved through adherence to procedures, with any deviations being reported and investigated as non-conformances as described in *QP-GEN-0005 Control of Non-Conformances*.
- b) Management and personnel are free from any undue internal and external commercial, financial or other pressures and influences that may adversely affect the quality of their work. This is implemented through adequate provision of resources as defined in *MP-GEN-0001 Management of the Laboratory* and *MP-GEN-0026 Code of Conduct for Laboratory Personnel & Confidentiality Statement*.
- c) The Department of Pathology ensures that there can be no conflict of interest for personnel involved in or with influence on the examination of primary samples. This is achieved through the maintenance of contracts of employment and job descriptions identifying responsibilities for each position which identify, manage and prevent a conflict of interest when testing. This is implemented through the *ED-GEN-0134 Public Service Management (Recruitments and Appointments) Act 2004* and *ED-GEN-0132 Ethics in Public Office Acts 1995 and 2012* and *MP-GEN-0026 Code of Conduct for Laboratory Personnel & Confidentiality Statement*.

Where potential conflicts in competing interests may exist, they shall be openly and appropriately declared.

- d) There are appropriate procedures to ensure that staff treats human samples, tissues or remains according to relevant legal requirements.

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- e) Our Lady's Hospital policy with regard to patient confidentiality is strictly adhered to. Each employee is contractually bound to ensure patient confidentiality and data protection as described in *ED-GEN-0003 HSE Codes of Standards and Behaviour* and *MP-GEN-0011 Management of Data and Information*. Breaches of confidentiality are dealt with as defined in *ED-GEN-0131 Disciplinary Procedure for Employees of the Health Service Executive (January 2007)*, *MF-GEN-0118 GDPR for Laboratory Personnel with regard to Training and CPD folders*.

#### **4.1.1.4 Laboratory Director**

The Laboratory is directed by Dr Su Maung, Consultant Haematologist.

The responsibilities of the Laboratory Director include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory

The Laboratory Director delegates selected duties and/or responsibilities to qualified personnel; however, the Laboratory Director maintains the ultimate responsibility for the overall operation and administration of the laboratory.

The duties and responsibilities of the Laboratory Director are documented in *MI-GEN-0006 Laboratory Director Roles & Responsibilities in Our Lady's Hospital, Navan*.

The Laboratory Director has the necessary competence, authority and resources to fulfil the requirements of ISO15189.

The Laboratory Director is responsible for the following:

- a) To provide effective leadership of the medical laboratory service, and delegating to the Chief Medical Scientist budget planning and financial management, in accordance with institutional assignment of such responsibilities according to *MP-GEN-0001 Management of the Laboratory*;
- b) To relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community and the patient population served and providers of formal agreements, when required according to *MP-GEN-0001 Management of the Laboratory*;
- c) To ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users described according to *MP-GEN-0017 Pathology Training Policy*;
- d) To ensure the implementation of the quality policy;



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- e) To implement a safe laboratory environment in compliance with good practice and applicable requirements according to *MP-GEN-0007 Staff Health and Safety Manual*, *MP-GEN-0004 Management of Clinical Material* and *LP-GEN-0016 Cleaning in the Laboratory*.
- f) To ensure that Consultants serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate according to *QP-GEN-0007 Advisory Services*.
- g) To ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results according to *QP-GEN-0007 Advisory Services*.
- h) To select and monitor laboratory suppliers according to *MP-GEN-0016 Management and Review of Contracts*;
- i) To select referral laboratories and monitor the quality of their service according to *MP-GEN-0016 Management and Review of Contracts*;
- j) To provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations according to *MP-GEN-0017 Pathology Training Policy*;
- k) To define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services according to *QP-GEN-0004 Continual Improvement*;
- l) To monitor all work performed in the laboratory to determine that clinically relevant information is being generated according to *QP-GEN-0004 Continual Improvement*;
- m) To address any complaint, request or suggestion from staff and/or users of laboratory services according *QP-GEN-0008 Complaints Procedure*.
- n) To delegate to the Chief Medical Scientist responsibility to design and implement a contingency plan that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable. Refer to *MP-GEN-0001 Management of the Laboratory*;
- o) To delegate to the Chief Medical Scientist the responsibility to plan and direct research and development, where appropriate according to *MP-GEN-0001 Management of the Laboratory*;

#### **4.1.2 Management Responsibility**

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#### **4.1.2.1 Management Commitment**

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

- a) Communicating to laboratory personnel the importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements according to *MP-GEN-0001 Management of the Laboratory*;
- b) Establishing the quality policy ensuring the quality objectives and planning are established;
- c) Defining responsibilities, authorities and interrelationships of all personnel according to *MP-GEN-0001 Management of the Laboratory*;
- d) Establishing communication processes according to *MP-GEN-0001 Management of the Laboratory* and *MP-GEN-0020 Management Review Procedure*;
- e) Appointing a Quality Co-ordinator;
- f) Conducting management reviews according to the *MP-GEN-0020 Management Review Procedure*
- g) Ensuring that all personnel are competent to perform their assigned activities according to the *MP-GEN-0017 Pathology Training Policy*;
- h) Ensuring availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities according to *MP-GEN-0001 Management of the Laboratory*;

#### **4.1.2.2 Needs of Users**

The Department of Pathology in Our Lady's Hospital provides the services outlined in section 1.2. Laboratory management ensures that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the service. The services of the Department of Pathology include appropriate interpretation and advisory services, and are designed to meet the needs of patients and all hospital personnel responsible for patient care. Refer to Table 2. *Department of Pathology Services*.

**Table 2. Department of Pathology Services**

<b>SERVICE NAME</b>	<b>SERVICE DESCRIPTION</b>
Blood Bank	<ul style="list-style-type: none"> <li>The Blood Bank comprises of the Blood Transfusion Laboratory and Haemovigilance service.</li> <li>Opening hours: 8.30-18.30 Monday – Friday. Emergency on-call service operates outside these hours.</li> </ul>

**Department of Pathology, Our Lady's Hospital**

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<b>SERVICE NAME</b>	<b>SERVICE DESCRIPTION</b>
	<ul style="list-style-type: none"> <li>The Blood Transfusion Laboratory offers comprehensive laboratory service including: <ul style="list-style-type: none"> <li>Blood Grouping and Antibody Screening, Antibody Identification (Inconclusive antibody panels are referred to the Irish Blood Transfusion Service for investigation)</li> <li>Cross-matching of blood during routine hours and urgent requests on call.</li> <li>Direct Coombs Test (DCT), Phenotyping/Antigen Typing</li> <li>Suspected Transfusion Reaction Investigation (if necessary)</li> </ul> Ref.: <i>LF-BT-0111 Blood Transfusion Schedule of Testing</i> </li> <li>Blood and Blood products (Plasma, PCC and Fibrinogen and other clotting factors) are stored in the Blood Transfusion laboratory. Platelets are ordered from the Irish Blood Transfusion Service when requested by a clinician.</li> <li><b>Routine Cross-matching</b> <ul style="list-style-type: none"> <li>Cross-matched blood is made available for routine transfusions and for operation cover in accordance with the <i>HF-GEN-0003 Maximum Blood Ordering Schedule</i> in place for Orthopaedics and General Surgery.</li> </ul> </li> <li><b>Emergency Cross-matching</b> <ul style="list-style-type: none"> <li>Two emergency O Rh (D) Negative, K, C, E negative units are available for emergency transfusion if necessary (<i>LP-BT-0016 Emergency Release of Blood</i>).</li> </ul> </li> <li>Shortdated blood is re-routed to Our Lady of Lourdes Hospital, Drogheda.</li> <li>The Haemovigilance service provides the following: <ul style="list-style-type: none"> <li>Haemovigilance and Traceability of all Blood Products.</li> <li>A reporting service to the National Haemovigilance Office as described in <i>HP-GENGEN-0006 The Reporting of SAEs/SARs/Near Misses to the National Haemovigilance Office</i>.</li> <li>Education and training to all clinical staff involved in the blood transfusion chain.</li> </ul> </li> </ul>
Haematology	<ul style="list-style-type: none"> <li>The Haematology Department provides routine and emergency testing of samples. Ref.: <i>QF-HAEM-0004 Haematology Schedule of Testing</i></li> <li>Routine hours are 08.30-18.30 Monday to Friday (excluding Bank Holidays)</li> <li>An emergency on-call service is available at all other times.</li> </ul>
Biochemistry	<ul style="list-style-type: none"> <li>The Biochemistry Department provides routine and emergency testing of samples. Ref.: <i>QF-BIO-0007 Biochemistry Schedule of Testing</i>.</li> <li>Routine hours are 08.30-18.30 Monday to Friday (excluding Bank Holidays)</li> <li>An emergency on-call service is available at all other times.</li> </ul>
Microbiology	<ul style="list-style-type: none"> <li>The Microbiology Department provides routine and emergency testing of samples and surveillance as appropriate. Ref.: <i>QF-MIC-0012 Microbiology Schedule of Testing</i>.</li> <li>Routine hours are 08.30-18.30 Monday to Friday (excluding Bank Holidays)</li> <li>An emergency on-call service is available at all other times.</li> </ul>
Phlebotomy	<ul style="list-style-type: none"> <li>The Phlebotomy Service is provided by personnel trained in phlebotomy techniques and is located in the Out-Patient's Department.</li> <li>The service operates from Monday to Friday 9.00am – 4.45pm taking samples from hospital patients.</li> <li>On week-ends and bank holidays, samples are taken by the phlebotomist on mornings only. Outside this time, trained nursing and medical staff perform phlebotomy.</li> </ul>
Consultant	<ul style="list-style-type: none"> <li>Advisory services are provided by Haematologist (Dr Su Maung) for Haematology and Blood Bank. Advice on-call is provided by the Haematology Clinical team in MMUH.</li> <li>Advisory services are provided by Microbiologist (Dr Emilia Manwa) for Microbiology.</li> <li>Advisory Services for Biochemistry are provided by a Consultant Chemical Pathologist (Dr Michael Louw).</li> </ul>

#### 4.1.2.3 QF-GEN-0146 Quality Policy

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Our Lady's Hospital Navan plays an important role in the provision of health services in the North East region. The Department of Pathology is committed to providing a service of the highest quality and shall be aware and take in to consideration the needs and requirements of its users.

The Mission Statement of the Department of Pathology is:

***'Our purpose is to contribute to improvement of the health and well-being of the people in the North-East'***

In order to ensure that the needs and requirements of users are met, the Department of Pathology implements the Quality Policy by:

- Ensuring the policy is appropriate to the purpose of the organisation;
- Including a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of ISO 15189 and continual improvement of the quality of the laboratory services;
- Providing a framework for establishing and reviewing quality objectives;
- Ensuring that the policy is communicated and understood within the organisation;
- Treating Health and Safety as a prime focus for users and staff of the Department of Pathology;
- Upholding professional values and good professional practice through the provision of continuing education, training and professional development;
- Recruiting of staff, training and development at all levels to provide an effective and efficient service to its users;
- Providing and managing resources to ensure that laboratory examinations are processed to produce the highest quality results possible;
- Reporting results in ways which are timely, confidential, accurate and are supported by clinical advice and interpretation when required;
- Implementation of internal quality control, external quality assessment, audit and assessment of user satisfaction to continuously improve the quality of the service.
- Complying with all environmental legislation;
- Complying with all regulatory standards including ISO 15189, EU Directive 2002/98/EC, AML-BB including Article 14 and 15, INAB Regulations for the services and tests defined in the Quality Manual;
- Reviewing for continuing suitability

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Laboratory Director (Dr Su Maung)

Signed \_\_\_\_\_ Date: \_\_\_\_\_

Chief Medical Scientist (Ray O'Hare)

Signed \_\_\_\_\_ Date: \_\_\_\_\_

General Manager (Mr Ken Fitzgibbon)

#### **4.1.2.4 Quality Objectives and Planning**

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Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organisation in accordance with *MP-GEN-0001 Management of the Laboratory*. The quality objectives shall be to measure aspects of the pre-examination, examination and post-examination processes and shall be consistent with the quality policy.

Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements and the quality objectives in accordance with *QP-GEN-0004 Continual Improvement*.

Laboratory management shall ensure that the integrity of the quality management system is maintained when the changes to the quality management system are planned and implemented in accordance with *MP-GEN-0019 Management of Change Control*.

#### **4.1.2.5 Responsibility, Authority and Interrelationships**

The responsibilities, authorities and inter-relationships of each department are defined, documented and communicated within the Department of Pathology. The Department of Pathology Management Team consists of the Laboratory Director of the Department of Pathology, Laboratory Consultants, General Manager and the Chief Medical Scientist.

The Chief Medical Scientist reports to the General Manager on governance issues and operational issues. The Chief Medical Scientist reports to the Laboratory Director of the Department of Pathology and the relevant Laboratory Consultants on clinical matters.

##### ***Department of Pathology Management Team***

- Laboratory Director of the Department of Pathology
- Consultants
- General Manager
- Chief Medical Scientist

##### ***Department of Pathology Quality Teams***

- Consultants
- Chief Medical Scientist
- Quality Co-ordinator
- Medical Scientist Representatives (if required)
- IT Co-ordinator (if required)
- Senior Phlebotomist (if required)
- Haemovigilance Officer (Blood Transfusion)

The Consultants are responsible for:

- Directing/advising clinical issues
- Communicating directly with the Chief Medical Scientist

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- Providing advice on the choice of tests
- Providing advice on the use of laboratory services
- Interpretation of laboratory data
- Overseeing Haemovigilance/Traceability (Consultant Haematologist)
- Infection Prevention & Control (Microbiology)

**The Chief Medical Scientist is responsible for:**

- Reporting to the General Manager on management and governance issues
- Directing scientific issues
- Providing advise on the development of scientific tests
- Providing advise on the use of laboratory services
- Interpretation of laboratory data
- Implementing the Quality Management System

The Department of Pathology Management Team ensures that policies and procedures are in place to define responsibility, authority and interrelationships.

The organizational and management structure of the Department of Pathology and interrelationships of personnel in relation to the Quality Management System are illustrated in Appendix 1. *Organisational Chart for Our Lady's Hospital, Navan.*

The Department of Pathology Management Team ensures that policies and procedures are in place to address the following:

- a. The responsibilities of personnel involved in the examination of primary samples are defined by formal job descriptions. Signed job descriptions are in place for each position and are located in individual training folders. Department of Pathology personnel are provided with the appropriate authority and resources to carry out their duties as specified in their job descriptions. This is implemented through *MP-GEN-0001 Management of the Laboratory* and *MP-GEN-0005 Management of Personnel*.
- b. The Chief Medical Scientist is responsible for preparing, reviewing and updating relevant job descriptions in conjunction with the Human Resources Department. Table 3. *Key Functions of Personnel in the Department of Pathology* outlines the role, responsibility and deputy for key personnel.
- c. It is the Department of Pathology policy to ensure that personnel are adequately trained to perform procedures that have an impact on the quality of service supplied, as described in *MP-GEN-0017 Pathology Training Policy*.
- d. The Department of Pathology Management Team has overall responsibility to ensure adequate resources are in place to ensure the required quality of service is provided.

#### **4.1.2.6 Communication**

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There are established communication processes within the Department of Pathology which ensures that communication takes place regarding the effectiveness of the Quality Management System. This is carried out through the following:

- Annual Management Review Meeting (Ref.: *Agenda MF-GEN-0001*)
- Pathology Governance Meeting (Ref.: *Agenda MF-GEN-0114*)
- Quality Meetings (Ref.: *Agenda MF-GEN-0060*)
- Quarterly General Laboratory Meeting (Ref.: *Agenda MF-GEN-0061*)
- Quarterly Senior Meeting (Ref.: *Agenda MF-GEN-0120*)
- Hospital Transfusion Committee Meeting (Ref.: *Agenda HF-BB-0002*)

Laboratory pre-examination, examination and post examination processes are discussed at all of these meetings. Quality indicators are used to track the effectiveness of these processes and reports are produced periodically by the Quality Co-ordinator to track and trend progress.

Records are kept in hard copy of items discussed in communications and meetings and managed by the Quality Co-ordinator.

There are hospital Infection Prevention & Infection Control Meetings; committee members include a Consultant Physician, Consultant Microbiologist, Infection Prevention and Control Nurse, Antimicrobial Pharmacist, Quality & Risk Manager, General Services, Technical Services, Assistant Director of Nursing and Senior Medical Scientist. Prevention and Control Nurse monitors trends/rates in infection control data, 'alert organisms' e.g. MRSA, C.difficile, VRE, CRE etc. The Senior Medical Scientist and/or the Prevention and Control Nurse forward relevant data to the Consultant Microbiologist to disseminate data to the service users. The Department of Public Health collates information supplied by the Microbiology Department and forwards this to the Health Protection Surveillance Centre (HPSC). The primary objectives of the hospital Prevention and Infection Control Committee is to implement the 2007 HSE's 'Say No to Infection' plan and to achieve compliance with the 2009 HIQA National Standards for the Prevention of Healthcare Associated Infections. The Infection & Prevention Control Committee meet on a quarterly basis to discuss current issues and to plan for the implementation of the Infection Prevention Control programme.

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**Table 3. Key Functions of Personnel in the Department of Pathology**

<b>Role</b>	<b>Role Description</b>	<b>Responsibility within the QMS</b>	<b>Deputy</b>
General Manager	Ultimate responsibility for the administrative management of the department.	Provide resources for the Quality Management System	Senior Manager
Laboratory Director	Ultimate responsibility for clinical governance of the department.	Provide effective leadership and clinical direction. Chairs the Pathology Governance Meetings.	Consultant
Consultant	Clinical Advisor	Clinical advice and direction on departmental issues. Attendance at Pathology Governance , Quality Meetings and Annual Management Review meetings.	Consultant
Chief Medical Scientist	Manages the local governance and administrative activities in the Department of Pathology	Development & implementation of the Quality Management System, ensures adherence to the Quality Management System by all staff	Senior Medical Scientist/ Medical Scientist
Senior Medical Scientist	Manage technical matters on a daily basis as directed by the Chief Medical Scientist	Ensure adherence to the Quality Management System by all staff	Medical Scientist
Quality Co-ordinator	Fulfils the roles and responsibilities of a quality manager. Is responsible for the overall management of the Quality Management System	Development & implementation and maintenance of the QMS.	Chief Medical Scientist
Medical Scientist	Day to Day work-load	Adheres to the Quality Management System.	Medical Scientist
IT Co-ordinator	Manages the Laboratory Information System and any IT Issues.	Ensure that all requirements of Annex B of ISO 15189 are met	Chief Medical Scientist
Laboratory Aides	Specimen reception and any other duties specified by the Chief Medical Scientist	Adheres to the Quality Management System.	Medical Scientist
Haemovigilance Officer	Haemovigilance/Traceability	Ensures compliance with AML-GEN, Articles 14 & 15.	Senior Medical Scientist Blood Bank
Surveillance Scientist	Manages the collection, analysis and dissemination of all Healthcare Associated Infection data in the Our Lady's Hospital, Navan and the surrounding community.	To fully implement all the requirements of the HIQA National Standards for the Prevention and Control of Healthcare Associated Infection for Surveillance and provide a link between the Pathology Laboratory, Public Health and the Health Protection Surveillance Centre in relation to the surveillance and reporting of infectious diseases and antimicrobial resistance via CIDR and EARS-Net. Be responsible for the development, co-ordination and implementation of quality processes within Pathology and for all documentation required for Surveillance of pathogens and antimicrobial resistance patterns on direction of the Chief Medical Scientist, HPSC and Consultant Microbiologist	Senior Medical Scientist in Microbiology, Infection Prevention & Control Nurse, Antimicrobial Pharmacist, Chief Medical Scientist
Senior Phlebotomist	Manages the phlebotomy service	Specimen collection and dispatch of samples to the laboratory.	Phlebotomist

Ref.: MF-GEN-0072 List of Names of Personnel in Pathology Laboratories in OLHN



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#### 4.1.2.7 Quality Manager

The Quality Co-ordinator fulfils the roles and responsibilities of the Quality Manager in Our Lady's Hospital, Navan. The Quality Co-ordinator is responsible for ensuring that processes needed for the quality management system are established, implemented and maintained across the Department of Pathology.

The Quality Co-ordinator reports directly to the Chief Medical Scientist who has the authority to make or recommend changes on policy and resources, in conjunction with the Director of the Department of Pathology.

The Quality Co-ordinator ensures the promotion of awareness of users' needs and requirements throughout the laboratory organisation.

## 4.2 Quality Management System

### 4.2.1 General Requirements

The Department of Pathology documents, implements and maintains a quality management system and continually improve its effectiveness in accordance with the requirements of ISO 15189.

The quality management system provides for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users. The interaction of all pre-examination, examination and post examination activities is illustrated in QF-GEN-0063 *Process Flow for the Quality Management System*. Resources such as staff, facilities, equipment, process management (quality control, change control) materials, information technology, and techniques/methods are considered as part of the input resources. Also included, are strategic processes including the mission statement, leadership review and resource management. Participation in External Quality Assurance Schemes, internal audits and external assessments and monitoring quality indicators are systems used to support the output of test results.

Policies, processes, programmes, procedures and instructions are documented and communicated to all relevant personnel. The management ensures that the documents are understood and implemented. All personnel are required to read all procedures relevant to the Quality Management System and to the technical processes, including Haemovigilance & Traceability activities, in which they are involved. This is implemented through MP-GEN-0002 *Management of Documentation, Preparation and Control* and the MP-GEN-0017 *Pathology Training Policy*.

The Department of Pathology:

- a) Ensures the availability of resources and information necessary to support the operation and monitoring of processes as outlined in MP-GEN-0001 Management of

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the Laboratory, *QP-GEN-0002 Evaluation and Audits*, *QP-GEN-0005 Control of Non-Conformances* and *QP-GEN-0009 Risk Management Procedure*.

b) Monitors and evaluates the criteria and methods needed to ensure that both the operation and control of pre-examination, examination and post-examination processes for the quality management system are established, implemented and maintained. The Department of Pathology has an adequate internal quality control procedure in place *LM-BT-0001 Reagent Quality Control*. They also participate in External Quality Assurance (EQA) Schemes which is implemented through the procedure for External Quality Assurance as per *QP-GEN-0003 External Quality Assessment*. They are also monitored through tracking and trending non-conformances, internal and external audit and risk assessments. Preventive actions are put in place as required.

c) Determines criteria and methods needed to ensure that both the operation and control of these processes are effective as per *MP-GEN-0001 Management of the Laboratory*. Actions are implemented as necessary to achieve planned results and continual improvement of these processes. A list of quality objectives is compiled at the beginning of each year to present to the Annual Management Review as the list of goals for the forthcoming year.

## **4.2.2 Documentation Requirements**

### **4.2.2.1 General**

The quality management system documentation includes:

- a) Statements of a quality policy and quality objectives
- b) The Quality Manual which describes the operation and management of the quality management system
- c) Procedures and records required by ISO 15189
- d) Documents and records determined by the laboratory to ensure the effective planning, operation and control of its processes
- e) Copies of applicable regulations, standards and other normative documents. These are compiled and reviewed annually as the master list of external documents and they are stored in Q-Pulse under ED-GEN. The number of the list will relate to different lists of external documents.

The documentation is in both paper and electronic format and is readily accessible and protected from unauthorised changes and undue deterioration. The electronic format is available in Q-Pulse. Controlled hard copy Standard Operating Procedures are used in the laboratory as a source of information. *LP-GEN-0007 User Manual* is available on the J drive.

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#### 4.2.2.2 Quality Manual

The Quality Manual is reviewed at regular intervals of 2 years or when required due to a change in regulations/personnel/services etc. This is implemented through *MP-GEN-0002 Management of Documentation, Preparation and Control*.

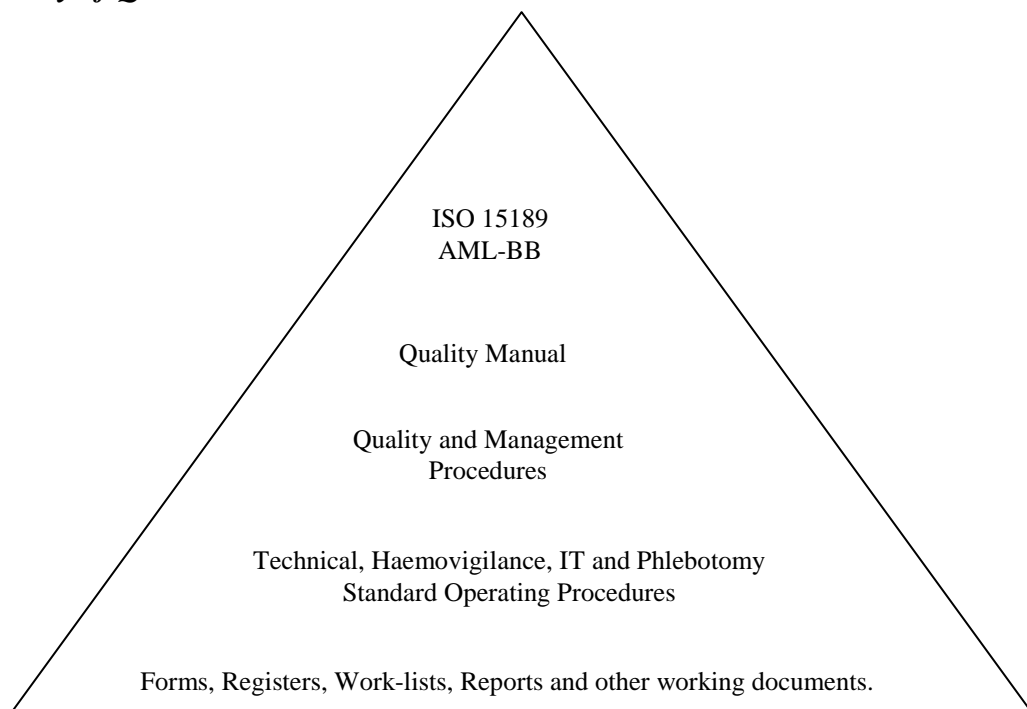
The laboratory has established and maintains a Quality Manual which includes:

- a) The Quality Policy
- b) A description of the scope of the Quality Management System (QMS)

A presentation of the organization and management structure of the laboratory and its place in the parent organization as outlined in *QF-GEN-0060 Pathology Laboratory Organisational Chart for Our Lady's Hospital, Navan*.

- c) A description of the roles and responsibilities of laboratory management (including the Laboratory Director and Quality Co-ordinator) to ensure compliance with ISO 15189.
- d) A description of the structure and relationships of the documentation used in the quality management system. This is implemented through *MP-GEN-0002 Management of Documentation Preparation and Control*. The hierarchy of the documentation system is described in Figure 1. *Hierarchy of QMS Documentation*.

**Figure 1. Hierarchy of QMS Documentation.**



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- e) The documented policies established for the quality management system and reference to the managerial and technical activities that support them. The Department of Pathology management implements plans and procedures which regularly monitor and demonstrate proper calibration and function of instruments, reagents and analytical systems.

All personnel have access and are instructed on the use and application of the Quality Manual, all referenced documents and the requirements for their implementation.

### **4.3 Document Control**

The laboratory controls documents required by the quality management system and ensures that unintended use of any obsolete documents is prevented.

Documents considered for control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements and documents of external origin such as regulations, standards and text books from which examination procedures are taken.

*MP-GEN-0002 Management of Documentation, Preparation and Control* describes the method by which the Department of Pathology controls all documents, including procedures, forms and information, from both internal and external sources.

The Document Control System is an electronic system i.e. Q-Pulse. Where there is a requirement for a change to a document due to a change in practice, procedure, material, and equipment etc., the change is requested, assessed, approved and authorised as per *MP-GEN-0019 Management of Change Control*.

All documents are retained for a defined period. The retention period meet minimum requirements of the Royal College of Pathologists.

Master copies of documents are maintained as hardcopies or on Q-Pulse.

The procedure *MP-GEN-0002 Management of Documentation, Preparation and Control* ensures that:

- a) All documents issued as part of the Quality Management System are reviewed and approved by authorized personnel prior to issue.
  - **Quality** – This review is performed by the Quality Co-ordinator.
  - **Technical** – This review is performed by a person with suitable knowledge of the discipline in question. For laboratory documents, this is the Chief Medical Scientist. For Haemovigilance/Traceability, this is the Haemovigilance Officer. For Phlebotomy documents, this is the Senior Phlebotomist.

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- **Management** – This review is performed by the Chief Medical Scientist/Senior Medical Scientist.
  - **Clinical** – This review is performed by the relevant Consultant.
- b) A unique Document Number, allocated by the Quality Co-ordinator from the *Documentation Register*. This is made up of four distinct units e.g. QP-GEN-0001.  
The units are as follows:

- The first unit describes the procedural activity and document type
- The second unit defines the department to which the document applies.
- The third unit defines the actual number of the document. This number is composed of four digits, starting with 0001.

A *Documentation Register* is maintained on Q-Pulse identifying current valid versions of each document, their distribution and the following information:

- Document Title
- Document unique identifier on each page
- Source identification – The source is identifiable from the unique

Document Number, examples as follows:

Management Procedure	MP
Management Form	MF
Quality Manual	QMn
Quality Procedure	QP
Quality Form	QF
Laboratory Procedure	LP
Laboratory Form	LF
Laboratory Instruction	LI
Haemovigilance Procedure	HP
Laboratory Manual	LMn
External Document	ED
Effective Date	
Page number to total number of pages [e.g. page 1 of 5]	
Personnel responsible for approval of document	
Revision Number	

- c) Current authorised revisions are identified by means of the document register. The distribution of all documents, either electronic or paper copies, is recorded on Q-Pulse in the Distribution List.
- d) Only currently authorized versions of appropriate documents are available for active use at relevant locations.
- e) *MP-GEN-0019 Management of Change Control* documents how changes to documents maintained in Q-Pulse are to be made and controlled.

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- f) Changes to documents are identified.
- g) Documents remain legible from revision to revision and the review history is stored in Q-Pulse.
- h) All documents are reviewed at least every two years for adequacy and revised when necessary. All revisions are authorised prior to implementation.
- i) Obsolete controlled documents are placed in the obsolete file on Q-Pulse. Hard copies are destroyed and information is recorded on Q-Pulse.
- j) One copy of an obsolete controlled document is retained on Q-Pulse.

#### **4.4 Service Agreements**

##### **4.4.1 Establishment of Service Agreements**

The services of the Department of Pathology are described in the *LP-GEN-0007 User Manual*.

Contractual arrangements between the Department of Pathology and the hospital wards, internal and external locations are defined by the request forms as follows:

- *LF-GEN-0011 Blood Transfusion Request Form* which is used to requisition the tests related to the Blood Bank
- *LF-GEN-0019 Pathology General Request Form* which is used to requisition the routine tests related to Haematology and Biochemistry,
- *LF-BIO-0024 Troponin-I Request Form* which is used to requisition Troponin-I,
- *LF-BIO-003 Gentamicin/Vancomycin Request Form* which is used to order Genatmicin or Vancomycin Levels
- *LF-GEN-0023 Microbiology Request Form* which is used to requisition Microbiology tests

In accordance with *MP-GEN-0016 Management and Review of Contracts*. Each request accepted by the laboratory for examinations is considered an agreement. Acceptance of the contract in the Department of Pathology is based on the incoming acceptance process as per *LP-BT-0001 Specimen Handling in Blood Transfusion* and *LP-GEN-0014 Specimen Handling in Biochemistry, Immunochemistry and Haematology*, *LP-MIC-0063 Specimen Reception in the Microbiology Laboratory*.

Agreements to provide medical laboratory services take into account the request, the examination and the report. The agreement specifies the information needed on the request to ensure appropriate examination and result interpretation.

Only requests on the official request forms are accepted by the Department of Pathology. The acceptance of a contract is based on the incoming inspection

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process. Checks are performed upon receipt of specimens and there are mandatory requirements which the specimens must meet in order to be successfully processed. If incoming inspection process fails i.e. if sufficient requirements are not met, the customer is informed by phone and a repeat specimen may be requested. All rejected contracts are documented on the non-conformance register.

Review of contracts with customer is performed periodically by the Department of Pathology Management Team using *LF-GEN-0002 Quality Assurance Confirmation Form*. This ensures that:

- a) Requirements, including the methods to be used, are adequately defined, documented and understood by the Department of Pathology and the Client / User of the Service.
- b) The Department of Pathology has suitable physical resources and capacity to meet the requirements.
- c) There is adequate numbers of skilled personnel, who have the required qualifications, expertise and relevant training, necessary to perform the required examinations in accordance with *MP-GEN-0017 Pathology Training Policy*. The Department of Pathology provides access to the clinical advisory services of Consultants to all users of the services. This also includes a review of participation in External Inter-Laboratory Quality Assurance Schemes in order to determine uncertainties of measurement, limits of detection and confidence limits.
- d) Appropriate procedures selected are able to meet the contract requirements and clinical needs (section 5.5) of the customer.
- e) Customers and users are informed of deviations from the agreement that impact upon the examination results.

As per procedure, *MP-GEN-0016 Management and Review of Contracts* if a contract needs to be amended after work has commenced, the contract review process is repeated and any amendments are communicated to the customer. This amendment is communicated on the reports issued with the results. Where additional testing/blood products are required on an original sample, an additional form is required. In an emergency situation the amendments are communicated to the customer by telephone and then followed up with the required form at later time.

Any deviation from the agreed service to be provided will be reported and investigated as a non-conformance or reported as a 'Planned Deviation' through *QP-GEN-0005 Control of Non-Conformances*. Affected users will be informed by way of a memo. The document number of the memo will be referenced on the non-conformance pertaining to the deviation.

Where a change to the contract between the Department of Pathology and the Referral Laboratory affects the service provided, users will be informed of the change, prior to implementation, as described in *MP-GEN-0019 Management of*

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*Change Control*, usually by way of a memo, which is registered on Q-Pulse in the documentation module under 'Memos'.

- f) Reference is made to any work by the Department of Pathology to a referral laboratory.

Records of reviews including any significant changes and pertinent discussions are maintained and include:

- Minutes of Meetings
- Customer Satisfaction Survey data and reports
- Customer Complaints
- Change Request on Q-Pulse
- Laboratory Test Request Forms

Any changes are documented through *MP-GEN-0019 Management of Change Control*.

The laboratory does not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an inducement for the referral of examinations or patients or interfere with the practitioner's independent assessment of what is best for the patient.

#### **4.4.2 Review of Service Agreements**

Reviews of agreements to provide medical laboratory services include all aspects of the agreement. Records of these reviews include any changes to the agreement and any pertinent discussions.

User satisfaction surveys which are carried out annually are used as a forum to review the contract. Review and changes may be made following discussion at the Quality Meetings and/or the Pathology Governance Meetings.

When an agreement needs to be amended after laboratory services have commenced, the same agreement review process will be repeated and any amendments will be communicated to all affected parties.

### **4.5 Examination by Referral Laboratories**

#### **4.5.1 Selecting and Evaluating Referral Laboratories**

*MP-GEN-0016 Management and Review of Contracts* describes the system in use for evaluating, selecting and using referral laboratories.

The procedure ensures that the following conditions are met:

- a) The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory, monitoring the



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quality of the performance and ensuring that the referral laboratories are competent to perform the requested examinations.

- b) The Department of Pathology operates an appropriate system for evaluating and selecting referral laboratories. Arrangements with referral laboratories are reviewed and evaluated periodically to ensure compliance with the relevant parts of ISO 15189.
- c) Records of such periodic reviews are maintained.
- d) A register of all referral laboratories is maintained.
- e) Requests and results of all samples are kept for a pre-defined period.

#### **4.5.2 Provision of Examination Results**

The following circumstances may require the referral of accredited tests:

- Following equipment breakdown and where urgent specimens must be processed and resulted immediately and where a backup methodology is not available or practicable
- In the case of the Blood Transfusion, where external serological investigations are required to confirm or identify a pattern of results e.g. complex antibody investigation including provision of compatibility services by the Irish Blood Transfusion Service.
- In the case of Haematology, Biochemistry and Microbiology, where the tests requested are not processed in the Haematology, Biochemistry or Microbiology Departments.

Unless otherwise specified in the agreement, the laboratory (and not the referral laboratory) is responsible for ensuring that examination results of the referral laboratory are provided to the person making the request. As described in *MP-GEN-0014 Reporting of Results*, it is the policy of the Department of Pathology to ensure that results, (specifically all essential elements of results) are returned to the requesting clinician.

The Department Of Pathology retains a record of all referral tests specific to individual patients on Apex. In addition, in the Blood Bank, *LF-BT-0053 IBTS Referral Record Form* is used and this contains the details of all samples referred. In Haematology, *LF-HAEM-0040 Haemoglobin S Screening, Internal Quality Control and Test Results* and *LF-HAEM-0038 Record of Malaria Screen, Internal Quality Control and Patient Test Results* are used and they include the results of the referred tests for Sickle Cell and Malaria Screening.

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The name and address of the referral laboratory responsible for the examination result is clearly indicated on the result report. Results from the referral laboratory are issued directly to the requesting clinician. The comment 'Results received from referral laboratory' is entered on the LIS to confirm receipt of reports.

The laboratory adopts the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both the referring and the referral laboratories, this process is not hindered by commercial or financial considerations.

#### **4.5.3 Service Level Agreements**

A Service Level Agreement is set-up for the use of the referral laboratories. An annual Quality Assessment Confirmation *LF-GEN-0002 Quality Assessment Confirmation Form* is sent annually to the referral laboratories for completion.

#### **4.6 External Services and Supplies**

The procedures for the selection and purchasing of external services, equipment, reagents, consumable supplies and off-site archiving that affect the quality of services provided by the Department of Pathology are defined through the following procedures:

- *MP-GEN-0009 Procurement and Management of Equipment*
- *LP-GEN-0009 Equipment Validation*
- *MP-GEN-0016 Management and Review of Contracts*
- *QVP-GEN-0005 Validation Masterplan for Pathology Laboratory*
- *LP-BT-0002 Monitoring of Materials in Blood Transfusion*
- *LP-BIO-0007 Batch Acceptance of Reagents, Calibrators, Q.C. and Consumables*
- *LP-HAEM-0012 Batch Acceptance of Reagents in Haematology*
- *LP-MIC-0065 Batch Acceptance in Microbiology*

The Quality Co-ordinator maintains a list of equipment in use for Blood Bank, Haematology, Biochemistry and Microbiology, in the Asset Module in Q-Pulse. This list identifies at a minimum the following:

- Name / Title of item of Equipment
- Asset Number
- Model Number
- Manufacturer
- Supplier
- Criticality of the item of Equipment
- Validation carried out (Yes / No)
- Service Contract required (Yes/ No)

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- Calibration Required (Yes / No).
- Maintenance required (Yes / No)
- Service Contract set up and renewed (Yes / No)
- Date of Last Service
- Date next Service is due.

A log of reagents and consumables in use are also retained in each department.

The laboratory selects and approves suppliers annually based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfil this requirement. All suppliers who supply external services, equipment, reagents and consumables that affect the quality of service are required to complete *MF-GEN-0035 Supplier Questionnaire*. All information obtained through supplier postal audits is reviewed on *MF-GEN-0049 Evaluation of Supplier Form* and retained.

Where information provided on *MF-GEN-0049 Evaluation of Supplier Form* does not meet requirements, the Department of Pathology may request additional information or visit the supplier's premises to oversee the production facility and carry out an inspection audit to determine the suitability of the supplier.

Suppliers are listed in the Suppliers module in Q-Pulse. Documentation that confirms the suppliers conformance with its quality management system, SLAs/contracts are maintained in Q-Pulse. The laboratory monitors the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria.

*Ref.: MF-GEN-0049 Evaluation of Supplier Form.*

Purchased equipment that affects the quality of service are not used until they have been verified as complying with requirements defined in *VMP-GEN-0001 Validation Master Plan for the Pathology Laboratory*. The schedule and status of Preventative Maintenance for all items of equipment is logged in the Assets module in Q-Pulse.+

Reagents and consumables that affect the quality of the service are only used when expected results are achieved, as defined in the procedure *LP-BT-0002 Monitoring of Materials in Blood Transfusion*, *LP-BIO-0007 Batch Acceptance of Reagents, Calibrators, Q.C. and Consumables*, *LP-HAEM-0012 Batch Acceptance of Reagents in Haematology* and *LP-MIC-0065 Batch Acceptance in Microbiology*.

Non-conforming external services and supplies are reported and investigated through *QP-GEN-0005 Control of Non-Conformances* and discussed as required at Quality Meetings as described in *MP-GEN-0021 Quality Meetings*.

Postal Audits have been carried out on key suppliers in order to obtain documentation of conformance with their quality management system.

There is an inventory control system for supplies. Appropriate quality records of external services, supplies and purchased products are established and maintained for a period of time, as defined in the Quality Management System. This system includes the recording of lot numbers of all relevant reagents, control materials and

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calibrators, the date of receipt and the date the material is placed in service. All of these quality records are available for management review. This is implemented through the procedure *LP-BT-0002 Monitoring of Materials in Blood Transfusion*, *LP-BIO-0007 Batch Acceptance of Reagents, Calibrators, Q.C. and Consumables*, *LP-HAEM-0012 Batch Acceptance of Reagents in Haematology* and *LP-MIC-0065 Batch Acceptance in Microbiology*.

#### **4.7 Advisory Services**

In order to meet the needs of patients and all clinical personnel responsible for patient care, the Department of Pathology provides advisory services as required to all users, as described in *QP-GEN-0007 Advisory Services*.

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

- Advising on choice of examinations and use of the services, including type of sample, clinical indications and limitations of examination procedures and the requesting the examination *LP-GEN-0007 User Manual*.
- The Consultants are available to provide advice on all issues relating to the individual specialities including appropriate interpretation of tests to meet the needs of patients and all clinical personnel responsible for patient care. The Consultants are contactable 24 hours through the switchboard at Our Lady's Hospital Navan (OLHN). The rota is located at the switchboard of OLHN.
- Appropriate (qualified / experienced) scientific staff provides advice to clinicians / users on choice of examinations and use of services, including repeat frequency and type of sample required for testing. Where appropriate, interpretation of the results of examinations will be provided by either the Consultant or the Medical Scientist, as appropriate.
- Promoting the effective utilization of laboratory services.  
Meetings between Department of Pathology and Hospital staff e.g. Regional Hospital Blood Transfusion Committee, are held regularly regarding the use of the services and for the purpose of consultation on scientific and Haemovigilance & Traceability matters. The Consultant Haematologist responsible for Blood Bank gives advice on managing Serious Adverse Events and Reactions. The Microbiology Consultant gives advice on Infection Prevention & Control.

The National Haemovigilance Office provides advice (through the Haemovigilance Officer) on all Haemovigilance & Traceability related issues, in addition to issuing recommendations and providing training and education for both Medical Scientists and the Haemovigilance Officer. The Medical Consultant and Medical Scientific personnel at the Irish Blood Bank Service (I.B.T.S.) provide clinical advice as required.

- Consulting on scientific and logistic matters such as failure of samples to meet acceptance criteria

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#### **4.8 Resolution of Complaints**

The Department of Pathology documents and investigates all perceived or real grievances from Clinicians, patients or other related parties pertaining to any aspect of the services, through *QP-GEN-0008 Complaints Procedure*. The procedure describes the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties.

All complaints are raised as non-conformances on Q-Pulse as described in *QP-GEN-0005 Control of Non-Conformances*.

All complaints are investigated as per *QP-GEN-0008 Complaints Procedure* by the Quality Co-ordinator in conjunction with the Chief Medical Scientist. Based on the findings, suitable corrective and preventative actions are identified as appropriate, to prevent a recurrence of the issue. All investigative actions, findings, root cause analysis, description and categorisation of the complaint as well as immediate corrective actions and corrective actions taken are documented.

The medical significance of the complaint is always considered and resolution of complaint addresses any issue in this area.

In addition, *QP-GEN-0008 Complaints Procedure* is used to evaluate and monitor the perceived quality and appropriateness of the service provided by the Department of Pathology and its contribution to patient care.

As defined in *QP-GEN-0008 Complaints Procedure*, the Quality Co-ordinator is responsible for the tracking and trending of complaints, associated non-conformances and user feedback, thus enabling a review of effectiveness of Corrective (and Preventative Actions if applicable).

All complaints and user feedback are discussed at Quality Meetings as described in *MP-GEN-0021 Quality Meetings*.

#### **4.9 Identification and Control of Non-Conformances**

##### **4.9.1** The Department of Pathology implements a non-conformance system as per *QP-GEN-0005 Control of Non-Conformances* when it detects:

- A non-conformance in any aspect of the quality management system including pre-examination, examination or post examination processes that does not conform to its own procedures.
- The requirements of the Quality Management System that are not met.
- The requirements of the requesting clinician that are not met.
- Haemovigilance & Traceability requirements that are not met.

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All staff can raise a non-conformance. Investigation, resolution and implementation of appropriate corrective and preventative actions are performed in conjunction with the relevant department.

Non-Conformances can occur in many different areas and can be identified in many different ways such as quality control indicators, instrument calibrations, checking of consumable materials, staff comments, reporting and certificate checking, audits, complaints etc.

The Quality Co-ordinator is responsible for implementing and managing the Non-Conformance System which is managed through Q-Pulse.

*QP-GEN-0005 Control of Non-Conformances* is designed to ensure that:

- a) The Quality Co-ordinator is responsible for implementing and managing the Non-Conformance System. The Quality Co-ordinator investigates and resolves the non-conformance in conjunction with the Chief Medical Scientist, Haemovigilance Officer and Consultant as appropriate.
- b) The immediate actions to be taken in the event of a non-conformance are defined in *QP-GEN-0005 Control of Non-Conformances*. Actions to be taken include reporting, investigative actions, investigation of impact, Corrective and Preventative Actions, Identification of the Root Cause and Classification of the non-conformance.
- c) The immediate actions to be taken are defined.
- d) When a non-conformance has been identified which may impact upon other specimens being processed, examinations are halted and reports withheld as necessary. The responsibility for the halting of laboratory examinations lies with the Chief Medical Scientist. All affected clinicians / users of the service are informed of the halting and subsequent resumption of examinations by Chief Medical Scientist/Consultant as deemed appropriate. Corrective action is taken as soon as possible upon detection of the non-conformance. The timeframe for execution of corrective action is cognisant of the urgency of the incident. The target close out for non-conformances is up to 90 days depending on the nature of the non-conformance.
- e) The medical significance of the all non-conformance is considered and signed off by the appropriate Consultant.
- f) The results of non-conforming examinations already released are recalled or appropriately identified, as deemed necessary by the Chief Medical Scientist. Where reports with erroneous results have been released the procedure used for their retrieval, replacement and communication to the relevant clinician is detailed in *MP-GEN-0014 Reporting of Results*.
- g) The responsibility for authorisation of the resumption of examinations lies with the Consultant in conjunction with the Chief Medical Scientist.

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- h) Non-conformances are reported via Q-Pulse. The Quality Co-ordinator is responsible for the tracking and trending of non-conformances at regular intervals enabling a review of effectiveness of Corrective and Preventative Actions. Non-conformances and emerging trends are discussed at Monthly Quality Meetings and Management Review Meetings.

Following investigation / review of a non-conforming pre-examination, examination and post-examination process where it is found that it could recur or that there is doubt about the compliance the department with its own policies or procedures as stated in the Quality Manual, then trouble shoot/cause and analysis methods are used to identify, document and eliminate the root cause of this problem. This corrective action is promptly implemented. All supporting documentation is attached to the non-conformance.

As defined in *QP-GEN-0005 Control of Non-Conformances*, if there is a non-conformance which has an impact on results, the release of such results or review of previously released results will be investigated by the Chief Medical Scientist and the Consultant, as appropriate.

#### **4.10 Corrective Action**

*QP-GEN-0005 Control of Non-Conformances* ensures an investigative process to determine the cause of the problem is performed and includes the following:

- a) Reviews non-conformances
- b) Determines the root cause of non-conformances
- c) Evaluates the need for corrective action to ensure that non-conformances do not recur.
- d) The nature of the corrective action depends on the classification of the non-conformance and of its potential risk to the patient. This also applies to Haemovigilance & Traceability and Phlebotomy activities. Any changes required resulting from corrective action investigations are documented and implemented as described in *QP-GEN-0019 Management of Change Control*.
- e) The effectiveness of the corrective action is reviewed on an ongoing basis and discussed as required at Quality Review Meetings. A formal review of effectiveness of corrective actions is presented at the Annual Management Review.

When the identification of non-conformance or the corrective action investigation casts doubt on compliance with policies and procedures or the quality management system, the Department of Pathology Management ensures that appropriate areas of activity are audited in accordance with the *QP-GEN-0002 Internal & External Audit*. The results of the audits are discussed at Quality Review meetings and the

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Management Review Meetings as described in *MP-GEN-0021 Quality Meetings* and *MP-GEN-0001 Management of the Laboratory*.

Action taken at the time of the non-conformance to mitigate its immediate effects is considered “immediate” action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered “corrective” action.

#### **4.11 Preventative Action**

The Department of Pathology Management ensures that an appropriate form of preventative action is implemented. Preventative action is a pro-active, pre-emptive process for identifying opportunities for improvement rather than a reaction to the identification of complaints or non-conformances. Preventive action is taken in order to ensure required improvements or potential sources of non conformances identified are managed thus minimising non-conformances relating to technical or quality processes.

Where the implementation of preventative action requires a change to existing procedures, all changes are carried out in accordance with *MP-GEN-0019 Management of Change Control*.

Preventative actions regardless of their origin, contribute to continual improvement in the service as described in *QP-GEN-0004 Continual Improvement*.

The procedure describes the action to eliminate the causes of potential nonconformities in order to prevent their occurrence. The preventive actions are appropriate to the effects of the potential problems.

The procedure includes:

- a) Reviewing laboratory data and information to determine where potential non-conformances exist
- b) Determining the root cause of potential non-conformances
- c) Evaluating the need for preventive action to prevent the occurrence of nonconformities
- d) Determining and implementing preventive action needed
- e) Recording the results of the preventive action taken
- f) Reviewing the effectiveness of the preventive action taken. Tracking and trending of the non-conformances and the audit process provides a forum to review the effectiveness of the preventive actions. These reports are discussed at the quality meetings as described in *MP-GEN-0021 Quality Meetings*.



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#### 4.12 Continual Improvement

As indicated in *MP-GEN-0002 Management of Documentation, Preparation and Control*, all procedures are reviewed biennially, or as required. These reviews may identify potential sources of non-conformance or other opportunities for improvement in the Quality Management System or in Standard Operating Procedures. All changes are made in accordance with *QP-GEN-0019 Management of Change Control*.

Where a major change, as defined in *QP-GEN-0019 Management of Change Control*, is made as a corrective action to remove a source of non-conformance or to improve the Quality Management System, the effectiveness of the action is evaluated by discussion at a subsequent Quality Meeting. If required, the area may be audited to evaluate effectiveness.

The laboratory is continually improving the effectiveness of the quality management system, including pre-examination, examination and post-examination processes. Action plans for improvement are developed, documented and implemented as appropriate. Continual Improvement is addressed at Management Review Meetings, as described in *MP-GEN-0001 Management of the Laboratory*, through a systematic review of significant issues which have arisen in the course of the year in all aspects of the Quality Management System and the contribution of services to patient care.

Laboratory management ensures that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. When the continual improvement programme identifies opportunities for improvement, laboratory management addresses them regardless of where they occur. Laboratory management communicates to staff improvement plans and related goals.

Quality Indicators are reviewed and monitored, by the Quality Co-ordinator in conjunction with the Chief Medical Scientist, on an on-going basis in order to systematically monitor and evaluate the contribution of services to patient care. This is described in *QP-GEN-0004 Continual Improvement*.

All personnel involved in the delivery of services have access to suitable education and training opportunities, as described in *MP-GEN-0001 Management of the Laboratory*, and *QP-GEN-0004 Continual Improvement*.

#### 4.13 Control of Records

The identification, collection, indexing, access, storage, maintenance and safe disposal of documentation pertaining to the Quality Management System is implemented through the following procedures:

- *MP-GEN-0002 Management of Documentation, Preparation and Control*
- *MP-GEN-0003 Management of Process and Quality Records*

Retention and storage of pathological records and specimens are in accordance with the recommendations of the Royal College of Pathologists as they apply to the

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retention and storage of pathological records and specimens and also the INAB Regulations.

Records are created concurrently with performance of each activity that affects the quality of the examination.

All personnel involved in the delivery of services are required to read and sign off on *MP-GEN-0002 Management of Documentation, Preparation and Control* which stipulates that all records must be completed in a legible manner.

Records are stored on hard copy and by electronic means. The Department of Pathology take all possible steps to ensure that technical records are stored in an environment that prevents damage, deterioration or unauthorised access. Access to both the Laboratory Information System and Q-Pulse are password protected.

*MP-GEN-0002 Management of Documentation, Preparation and Control* stipulates the length of time that each type of documentation generated through the Quality Management System and documents pertaining to pre-examination, examination and post-examination processes are retained. Reported results are retrievable for as long as medically relevant or as required by regulation.

For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location.

These records include but are not limited to the following:

- a) Supplier selection and performance and changes to the approved supplier list
- b) Staff qualifications, staff training and competency records maintained in individual staff folders
- c) Request forms (including the patient chart or medical record only if used as the request form)
- d) Records of receipt of samples in the laboratory stored in the laboratory information system
- e) Information on reagents and materials used for examinations [e.g. lot documentation, certificates of supplies, package inserts]
- f) Laboratory work-books/work-sheets
- g) Instrument printouts and retained data and information
- h) Examination results and reports stored in the laboratory information system
- i) Instrument maintenance records, including internal and external calibration records
- j) Calibration functions and conversion factors

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- k) Quality control records
- l) Incident/accident records and action taken
- m) Accident records and action taken
- n) Risk Management records
- o) Nonconformities identified and immediate or corrective action taken logged on Q-Pulse
- p) Preventive action taken logged on Q-Pulse
- q) Complaints and action taken logged on Q-Pulse
- r) Records of internal and external audits
- s) Inter-laboratory comparisons of examination results
- t) Quality improvement records
- u) Minutes of meetings that record decisions made about the laboratory's quality management activities
- v) Records of management reviews

All of these quality and technical records are available for laboratory management review. A list of authorising signatures and the name printed in capitals allows traceability of the requesting clinician. Storage of Quality and Technical Record hard copies are externally contracted to Iron Mountain. There is a Service Level Agreement in place with Iron Mountain and Our Lady's Hospital, Navan.

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**Table 4 List of Blood Transfusion Records and their Associated Minimum Retention Times**

<b>Records</b>	<b>Minimum Retention Period</b>
Request forms (Blood Transfusion)	30 yrs (as contains signatures)
Request Forms (All other Departments)	1 Month
Examination results and reports	30 yrs
Instrument printouts	5 Years
Examination procedures	While method is current and 5 years
Laboratory work-books or sheets	30 yrs
Accession records	30 yrs
Calibration records and conversion factors	Life time of instrument and a minimum of 10 yrs
Quality control records	10 yrs
Complaints and action taken	5 yrs
Records of internal and external audits	5yrs
External quality assessment records /inter laboratory comparisons	5yrs
Quality improvement records	5 yrs
Instrument maintenance records, including internal and external calibration records	30yrs
Lot documentation, certificates of supplies, package inserts	30yrs
Incident/accident record and action taken	30yrs
Staff training and competency records	30yrs

#### **4.14 Evaluation and Audits**

##### **4.14.1 General**

The Department of Pathology implements *QP-GEN-0002 Evaluation and Audits*:

- To verify that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of the users.
- To ensure conformity to the quality management system
- To continually improve the effectiveness of the quality management system

In order to emphasise areas critically important to patient care, vertical audits of Haemovigilance activities and Traceability are carried out on an on-going basis by tracking blood and/or blood products from receipt to transfusion as per *HP-GEN-0007 Operation and Function of Haemovigilance Role*.

The Internal Audit Schedule is prepared by the Quality Co-ordinator and indicates the area to be audited, the month the audit is to take place, the auditor assigned.

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All elements of the Quality Management System are subject to internal audit once every twelve months.

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

Audits are performed by designated personnel who have undergone auditor training. Where possible, personnel do not audit their own activities. Auditors review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.

The laboratory reviews periodically sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as appropriate, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand. This is described in *QP-GEN-0004 Continual Improvement*. The review is completed in each laboratory using the audit *QF-GEN-0064 Review of Examinations Provided by the Laboratory*

#### **4.14.3 Assessment of User Feedback**

There is a procedure in place to describe how assessment of user feedback is managed *QP-GEN-0001 User Satisfaction*. The laboratory performs user satisfaction surveys annually to determine whether the service meets the needs and requirements of the users. The surveys include co-operation with the users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users. Records are kept of information collected and actions taken. Feedback is given when appropriate, to participants in surveys.

#### **4.14.4 Staff Suggestions**

The laboratory management encourages staff to make suggestions for the improvement of the laboratory service. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management are maintained using *QF-GEN-0061 Log of Staff Suggestions/Preventive Action/Continual Improvement* and entered on Q-Pulse if valid, following discussion at the general laboratory meeting.

#### **4.14.5 Internal Audit**

The laboratory conducts internal audits at planned intervals to determine whether all activities in the quality management system including pre-examination, examination and post-examination:

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- a) Conform to the requirements of ISO 15189 and to requirements established by the laboratory and
- b) Are implemented, effective and maintained

Audits are conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit programme takes into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined and documented.

Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors are, wherever resources permit, independent of the activity to be audited.

All elements of ISO 15189 as they relate to the services are audited at least once annually. The internal audit programme progressively addresses all aspects of the services. A horizontal audit is a detailed check of the efficacy of implementation of a particular aspect of the ISO15189 and AML-BB standards.

In addition, vertical audits are carried out periodically during the year. A vertical audit of a request is a detailed check that all the elements associated with a chosen examination are implemented (e.g. select a particular request form and audit its trail as follows: reprint the request form, locate the specimen, check IQC & EQA details, instrument maintenance, the report, interpretation etc).

Vertical audits of Haemovigilance/Traceability involve following a blood product from receipt at the Blood Bank to its final fate, ensuring that all defined Haemovigilance and traceability procedures were adhered to.

The Laboratory has a documented procedure which defines the responsibilities and requirements for planning and conducting audits and for reporting and maintaining records *QP-GEN-0002 Evaluation and Audits*. All Audit documentation is retained by the Quality Co-ordinator and they are responsible for the area being audited to ensure that appropriate action is promptly undertaken when non-conformances are identified. Corrective action is taken without undue delay to eliminate the causes of the detected non-conformances.

The results of internal audit are regularly evaluated by the Quality Co-ordinator and the decisions taken are documented, monitored, reviewed and acted upon. Any non-conformance detected through auditing is investigated as described in *QP-GEN-0005 Control of Non-Conformances*. The results of internal audits are discussed at the Quality Meetings and Management Reviews as described in *MP-GEN-0021 Quality Meetings* and *MP-GEN-0020 Management Review Procedure*, respectively.

#### **4.14.6 Risk Management**

There is a procedure in place to describe the risk management process *QP-GEN-0009 Risk Management Procedure*.

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The laboratory evaluates the impact of work processes and potential failures on examination results as they affect patient safety and modifies processes to reduce or eliminate the identified risks and document decisions and actions taken. Risk assessments are carried out on key areas of the pre-examination, examination and post examination processes to identify possible risks and to put controls in place to support potential vulnerable areas. All risk assessments are recorded on Q-Pulse.

#### 4.14.7 Quality Indicators

The laboratory establishes quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes. This is described in *QP-GEN-0004 Continual Improvement*.

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

The laboratory establishes quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care. All quality indicators have set target values.

Quality indicators are established through discussion at Quality meetings and the Annual Management review meeting. The indicators are reviewed bi-annually to ensure their continued appropriateness on *QF-GEN-0071 Quality Indicators Bi-Annual Audit*

The laboratory, in consultation with the users, establishes turnaround times for each of its examinations that reflect clinical needs. Turnaround times for all tests are included in *LP-GEN-0007 User Manual*. The laboratory periodically evaluates whether or not it is meeting the established turnaround times.

#### 4.14.8 Reviews by External Organizations

When reviews by external organizations indicate the laboratory has non-conformances or potential non-conformances, the laboratory takes appropriate immediate actions and, as appropriate, corrective or preventive action to ensure compliance with the requirements of ISO 15189. Records are kept of the reviews and of the corrective actions and preventive actions taken. Hard copy reports are produced through audit by the Irish National Accreditation Board. Copies of the non-conformances from these audits are stored on Q-Pulse.

### 4.15 Management Review

#### 4.15.1 General

All services are subject to annual review. The Annual Management Review, described in *MP-GEN-0001 Management of the Laboratory*, examines the continuing suitability and adequacy of services and their effectiveness and support of

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patient care. The need to introduce any necessary changes or improvements may also be identified.

In addition, Quality meetings, as described in *MP-GEN-0021 Quality Meetings*, are held to address individual aspects of the Quality Management System on an on-going basis.

The format of meetings is defined in *MP-GEN-0001 Management of the Laboratory* and *MP-GEN-0021 Quality Meetings* to ensure that results of the review are incorporated into a plan that includes goals, objectives, action plans, responsible personnel and the dates that actions are to be completed by.

#### **4.15.2 Review Input**

The Annual Management Review, Quality Meetings and Pathology Governance Committee cumulatively include information from the results of at least the following:

- a) The periodic review of requests and suitability of procedures and sample requirements
- b) Feedback from clinicians, patients and other parties
- c) Staff suggestions
- d) Outcome of recent internal audits
- e) Risk management
- f) Quality indicators for monitoring the laboratory's contribution to patient care
- g) Assessment by external bodies, e.g. Health Products Regulatory Authority, INAB
- h) The outcome of external quality assessment e.g. UK NEQAS, IEQAS, RIQAS, WEQAS, LabQuality
- i) Monitoring and resolution of complaints
- j) Evaluation of performance of suppliers
- k) Identification and control of Non-conformances
- l) Results of continuous improvement processes including current status of corrective and preventive actions
- m) Follow up actions from previous management reviews
- n) Changes in the volume and scope of work, personnel and premises that could affect the quality management system
- o) Recommendations for improvement, including technical requirements



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- p) Goals for the forth-coming year
- q) Reports from relevant managerial and supervisory personnel

#### **4.15.3 Review Activities**

The quality and appropriateness of the contribution of the Department of Pathology to patient care is monitored and evaluated objectively through the Management Review Meeting, Quality Meetings and Pathology Governance Committee Meetings and arising actions are discharged within an appropriate and agreed upon timeframe.

The various meetings analyse the input information for causes of nonconformities, trends and patterns that indicate process problems. It also includes assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

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

#### **4.15.4 Review Output**

Minutes of the findings and actions from all meetings are documented. The minutes document:

- a) Improvement of the effectiveness of the quality management system and its processes
- b) Improvement of services to users
- c) Resource needs

Findings and actions are implemented within the appropriate and agreed upon timeframes and are available for review by laboratory staff.

## **5. TECHNICAL REQUIREMENTS**

### **5.1 Personnel**

#### **5.1.1 General**

The laboratory has documented procedures for personnel management and maintains records for all personnel to indicate compliance with requirements. These include *MP-GEN-0005 Management of Personnel* and *MP-GEN-0011 Management of Data and Information*.

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The reporting and working relationships are demonstrated through the Appendix 1 QF-GEN-0060 Department of Pathology *Organisation Chart for Our Lady's Hospital, Navan*.

The Director of the Department of Pathology, Consultants, the Chief Medical Scientist, Senior Medical Scientists have responsibility for:

- The testing/advisory and consultative services offered by the Department of Pathology as appropriate
- The administration of the department including management of personnel and ensuring that sufficient resources (personnel, material, equipment) are available to meet the requirements of the service as appropriate
- Ensuring personnel are suitably qualified, trained and competent and also providing opportunities for continuing education as appropriate

The Chief Medical Scientist ensures 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 Traceability.

The Human Resources Department at Our Lady's Hospital ensure that all personnel working in the hospital, including personnel working within the Department of Pathology have the required qualifications (in accordance with national guidelines and regulations) and experience to carry out the duties relevant to their post within the organisation. See Table 5. *Responsibilities of Personnel* outlines the personnel responsible for the discharge of key tasks.

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**Table 5. Responsibilities of Personnel**

<b>Task</b>	<b>Description of Responsibility</b>	<b>Responsible</b>
a.	Provide advice on choice of test in the Department of Pathology and interpretation of laboratory results or data	Consultants
b.	Serve as an active member of the medical staff for the hospital	Consultants
c.	Relate and function effectively with: <ul style="list-style-type: none"> <li>Irish National Accreditation Board (INAB)</li> <li>HIQA</li> <li>Health Products Regulatory Authority</li> <li>General Manager</li> <li>The healthcare community within the Hospital i.e. Clinicians, Clinical Area</li> <li>National Haemovigilance Office (NHO)</li> <li>Infection Prevention &amp; Control</li> </ul>	Laboratory Director of Department of Pathology: Consultants Chief Medical Scientist Quality Co-ordinator  Haemovigilance Officer
d.	Define, implement and monitor standards of performance and quality improvements of the Medical Laboratory Service	Department of Pathology Management Team*
e.	Implementation of the Quality Management System and participation in any quality improvement committees within the hospital	Department of Pathology Management Team*
f.	Monitor all work performed in the Department of Pathology to ensure data is being generated and reported (Internal QC and EQA)	Department of Pathology Management Team*
g.	Ensure personnel performing laboratory tasks are suitably qualified, adequately trained and have the required experience	Chief Medical Scientist
h.	Plan, set goals, develop and allocate resources appropriate to the medical environment	Department of Pathology Management Team*
i.	Provide effective and efficient administration of the Department of Pathology, including budget planning and control with responsible financial management	Chief Medical Scientist
j.	Provide educational programmes for the Medical Laboratory staff and ensuring participation in education programmes provided by the Hospital	Chief Medical Scientist
k.	Plan and direct research and development performed in the Laboratory as required	Consultants Chief Medical Scientist
l.	Select and monitor all referral laboratories for quality of service	Consultants Chief Medical Scientist Quality Co-ordinator
m.	Implement a safe laboratory environment in compliance with legal requirements, hospital policy and laboratory department safety procedures	Department of Pathology Management Team*
n.	Address any complaint, request or suggestion from the users of the Department of Pathology	Department of Pathology Management Team*
o.	Ensure good staff morale	Department of Pathology Management Team*
p.	Ensuring requirements of EU Directive 2002/98/EC are met	Department of Pathology Management Team*

\*The Department of Pathology Management Team consists of the Laboratory Director of the Department of Pathology, Laboratory Consultants, the hospital General Manager and the Chief Medical Scientist.

### **5.1.2 Personnel Qualifications**

Records of the relevant educational and professional qualifications, training and experience, and competence of all personnel are stored in either the Department of Pathology or the Human Resources Department. Copies of all relevant qualifications are requested and checked for veracity by the Human Resources Department prior to the person taking up the post. These records include the following:

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- a) A certificate or licence is required by a person in order to practice in their profession
- b) A qualification recognised by the Academy of Medical Laboratory Sciences (AMLS) is required to work as a Medical Scientist.
- c) A nursing qualifications and registration with the Nursing Body in Ireland, Nursing and Midwifery Board of Ireland for the post of Haemovigilance Officer if the post is filled by a nurse.
- d) Registration with the Medical Council of Ireland and certificate of the Specialist Register for all Consultants.
- e) All qualifications or licenses are current and up to date, and are obtained by the HR personnel prior to the person taking up the post. This is implemented through the *Public Service Management (Recruitments and Appointments) Act 2004*.

### **5.1.3 Job descriptions**

Job descriptions are in place for all staff and retained in individual training folders. Written job descriptions are in place for all grades of personnel including:

- Laboratory Director
- Consultants
- Chief Medical Scientist
- Quality Co-ordinator
- Senior Medical Scientists
- Medical Scientists
- Haemovigilance Officer
- Phlebotomists
- Clerical

### **5.1.4 Personnel Introduction to the Organizational Environment**

The laboratory has a programme to introduce new staff to the organisation, the department or area in which the person will work the terms and conditions of employment and staff facilities as per *MF-GEN-0044 Laboratory Staff Induction Checklist for all new staff members*

### **5.1.5 Training**

*MP-GEN-0017 Pathology Training Policy*, *MP-GEN-0005 Management of Personnel* and *HP-GEN-0008 Haemovigilance Training* are the procedures that describe staff training. There is a training plan in place for all staff which ensures that they are suitably trained in all areas of the Quality Management System.

Only staff that hold the required qualifications, the applicable theoretical and practical background, recent experience and suitable training are authorised to make

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professional judgements with reference to examinations (scientific staff), Haemovigilance & Traceability and Phlebotomy activities (nursing/scientific staff). Professional judgements can be expressed as opinions, interpretations, predictions, simulations, models and values are in accordance with national, regional and local regulations. Personnel, including Haemovigilance & Traceability and Phlebotomy personnel, take part in regular professional development or other professional liaison.

This is implemented through the following procedures:

- *MP-GEN-0017 Pathology Training Policy*
- *MP-GEN-0005 Management of Personnel*
- *HP-GENGEN-0008 Haemovigilance Training*

The laboratory provides training for all personnel in areas that are relevant to their position. These include:

- The Quality Management System
- Assigned Work Processes and Procedures
- The Laboratory Information System (Apex). The LIS is managed and controlled by the Laboratory IT Co-ordinator. Design and management of the LIS is cognisant of the clauses of ISO 15189:2012. Procedures have been established that define who may use the LIS including access to patient data and who is authorised to enter and change patient results or modify computer programmes. Refer to *MP-GEN-0012 Management and Operation of Apex*. The audit trail feature of the LIS ensures that the identity of the staff member requesting and making entries and amendments to entries is recorded
- Health and Safety including the prevention or containment of the effects of adverse incidents. Staff are trained to prevent or contain the effects of adverse incidents. This is implemented through *MP-GEN-0007 Staff Health & Safety Manual*.
- Ethics
- Confidentiality of Patient Information. Confidentiality of information regarding patients is maintained by all personnel, including personnel involved in laboratory, Haemovigilance & Traceability and Phlebotomy activities as per their contracts of employment and their job descriptions. This is in accordance with *MP-GEN-0011 Management of Data and Information*.
- Haemovigilance & Traceability

Personnel that are undergoing training are supervised at all times. The effectiveness of the training is periodically reviewed.

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### 5.1.6 Competence Assessment

A comprehensive Training and Competency programme for all staff ensures that personnel are competent to perform their tasks. Competency testing is carried out on an on-going basis, as described in *MP-GEN-0017 Pathology Training Policy*, *MP-GEN-0005 Management of Personnel* and *HP-GEN-0008 Haemovigilance Training*. Competency training plans ensure that the competency of each member of routine and on-call staff will be assessed at least once annually, thus ensuring that they are competent to perform individual tasks. Refer to *LF-BT-0016 Competency Review for Rotating Blood Transfusion Laboratory Scientist*, *MF-BIO-0006 Biochemistry Training and Competency Programme for Non-Biochemistry On-call Staff*, *MF-BIO-0017 Biochemistry Certificate of Competency*, *LF-HAEM-0019 Annual Competency Review for Haematology Laboratory Scientists*, *LF-HAEM-0067 Haematology Tests Performance and Authorization: Competency Testing*, *LF-HAEM-0073 Interpretation of Data for Proficiency Testing*, *LF-HAEM-0096 Competency Assessment Questionnaire Haematology* and *LF-MIC-0012 Annual Competency in Gram Staining in Microbiology for On-call Medical Scientists*.

Re-training may be required in the corrective/preventative action associated with a non-conformance or complaint, as described in *QP-GEN-0005 Control of Non-Conformances*. This is organised by the Chief Medical Scientist and recorded in the individuals Training File.

Where a procedure is not fully understood, individual personnel are obliged to complete *MF-GEN-0003 Request for Re-Training* and discuss retraining needs with the Chief Medical Scientist. Re-training including competency assessment occurs on an annual basis for staff performing emergency on-call duty.

In addition, retraining is carried out when a member of staff returns from a leave of absence of greater than one year.

There is a plan in place for Internal & External Training and for On-going Competency Assessment of Laboratory Personnel. This is implemented through *MP-GEN-0017 Pathology Training Policy* and *MP-GEN-0005 Management of Personnel*. All training is documented and records retained in individual training folders for each laboratory staff member.

Competency of laboratory staff is assessed using a combination of approaches under the same conditions as the general working environment as follows:

- Direct observation of routine work processes and procedures, including all applicable safety practices
- Direct observation of equipment maintenance and function checks
- Monitoring the recording and reporting of examination results
- Review of Work Records
- Assessment of Problem Solving Skills
- Examination of specifically provided samples, such as previously examined samples, inter laboratory comparison materials or split samples

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### **5.1.7 Reviews of Staff Performance**

In addition to the assessment of technical competence, the laboratory ensures that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships. Ref. *MP-GEN-0006 Management of Annual Joint Review*.

Staff performing reviews receive appropriate training.

### **5.1.8 Continuing Education and Professional Development**

A continuing education programme is available to personnel who participate in managerial and technical processes. This is in accordance with *MP-GEN-0024 Continuing Education and Professional Development*. All personnel take part in continuing education. The effectiveness of the continuing education programme is periodically reviewed.

Personnel take part in regular professional development or other professional liaison activities.

### **5.1.9 Personnel Records**

Records of the relevant educational and professional qualifications, training and experience and assessments of competence of all personnel are maintained. These records are readily available and include the following:

- Educational and Professional Qualifications (held in the individual staff Training folders)
  - Certificate or License when applicable
  - Previous Work Experience (The Human Resources Department maintains references from previous employment. This is implemented through the *Public Service Management (Recruitments and Appointments) Act 2004*.)
  - Job Descriptions (held in individual Training Folders)
  - Introduction of New Staff to the Laboratory Environment
  - Training in Current Job Tasks (filed in individual Training folders)
- Competency Assessments (held in individual Training Folders).  
Competency assessment records are maintained for laboratory staff as per *MP-GEN-0017 Pathology Training Policy*, and *MP-GEN-0005 Management of Personnel* and are filed in individual Training Folders. Competency evaluations of non-laboratory personnel trained in Haemovigilance procedures/activities and Haemovigilance Officers are carried as per the procedures, *HP-GEN-0007 Operation and Function of the Haemovigilance Role* and *HP-GEN-0008 Haemovigilance Training*
- Records of competency assessments for Continuing Education and Achievements as defined in *MP-GEN-0017 Training Procedure for Laboratory Personnel*, *MP-GEN-0001 Management of the Laboratory*, *MP-GEN-0005 Management of Personnel* and *QP-GEN-0004 Continual Improvement*,

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continuing education programmes are available to staff at all levels involved in the delivery of services.

Scientific, Medical, Phlebotomy and Haemovigilance staff attends National and International meetings and seminars and other professional meetings for continued professional development and records of these are filed in individual Training Folders.

- Reviews of Staff Performance are held in individual files in the Chief Medical Scientist's Office
- Reports of Accidents and Exposure to Occupational Hazards.  
All staff are obliged to attend corporate training in Hand Washing. Manual Handling and Fire Safety Training are mandatory for all staff.  
Records of personal incidents / accidents are maintained in accordance with the requirements of MP-GEN-0007 *Staff Health & Safety Manual* and recorded on *Incident, Near Miss and Hazard Report Form*. Completed forms are then are forwarded to the Risk Manager at Our Lady's Hospital who assesses the incident
- Immunisation Status, when relevant to Assigned Duties.  
Other records available to authorized persons relating to personnel health may include records of exposure to occupational hazards – These are maintained individual files in the Occupational Health Department, St. Theresa's Residence, OLOL Complex, Drogheda, Co. Louth.

## **5.2 Accommodation and Environmental Conditions**

### **5.2.1 General**

There is a procedure in place to describe the facilities in the laboratory *MP-GEN-0025 Facilities in the Department of Pathology*. The Department of Pathology facilities are ergonomically designed to ensure that the workload can be performed without compromising the quality of work, quality control procedures, health and safety of personnel, patients and visitors. Adequate space is available for specimen collection, specimen reception, handling, despatch and Haemovigilance and traceability activities in the department.

The laboratory evaluates and determines the sufficiency and adequacy of the space allocated for the performance of the work.

### **5.2.2 Laboratory and Office Facilities**

The design and environment of the Department of Pathology is suitable for the tasks carried out therein. The environments in which the primary sample collection and examination / testing are performed is controlled so that samples taken or results of testing performed are valid and not adversely affected in quality.

The design of the Department of Pathology permits correct performance of examinations due to the following:

- Adequate energy sources



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- Adequate lighting
- Adequate ventilation
- Adequate heating
- Adequate water supply
- Adequate waste and refuse disposal
- Controlled environmental conditions.

The Department of Pathology has procedures for checking that the environment does not adversely affect the performance of specimen collection and equipment. Attention is paid to overall cleanliness and temperatures relevant to the technical activities concerned. Environmental conditions are routinely monitored either manually or by the Rees temperature monitoring system. This is implemented through *MP-GEN-0025 Facilities in the Department of Pathology*. Environmental conditions are also assessed through regular audits.

The Department of Pathology is designed such that there is clear segregation between clerical and laboratory areas resulting in efficiency of its operation. This ensures the comfort of its occupants and minimises the risk of injury and occupational illness. This is implemented through *MP-GEN-0025 Facilities in the Department of Pathology*. The Department of Pathology and associated office facilities provide an environment suitable for the tasks to be undertaken by ensuring that access to and use of areas affecting the quality of examinations is controlled by means of a swipe card security system, ensuring that access to the laboratory is traceable. An electronic swipe card access security system is in place to ensure only authorised staff have access to the Department of Pathology, as described in *MP-GEN-0025 Facilities in the Department of Pathology*.

The laboratory also ensures that:

- a) Access to, and use of, areas affecting the quality of the examinations are controlled. Appropriate security measures are in place to safeguard samples and resources from unauthorized access.
- b) Medical information, patient samples and laboratory resources are safeguarded from unauthorised access.
- c) Facilities for examination allow for correct performance of examinations. These include energy sources, lighting, ventilation, noise, water, waste disposal and environment conditions
- d) Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information and implemented through *MP-GEN-0025 Facilities in the Department of Pathology*.

These include:

- E-mail
- Meetings (all minuted)

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- Notice Boards/Memos
- Message Logs
- Handover Logs

e) Safety facilities and devices are provided where appropriate and their functioning regularly verified.

### **5.2.3 Storage Facilities**

Storage space and conditions are provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.

This is implemented through:

- *MP-GEN-0002 Management of Documentation, Preparation and Control*
- *LP-BT-0002 Monitoring of Materials in Blood Transfusion*
- *LP-BIO-0007 Batch Acceptance of Reagents, Calibrators, Q.C. and Consumables*
- *LP-HAEM-0012 Batch Acceptance of Reagents in Haematology*
- *MP-GEN-0004 Management of Clinical Material*
- *LP-MIC-0065 Batch Acceptance in Microbiology*

Storage and disposable facilities for dangerous materials are appropriate to the hazards of the materials and as specified by applicable requirements.

Appropriate Safety signage is used where there are potential hazards. Hazardous chemicals are stored in the chemical cabinets. The fume cupboard is used to dispense hazardous materials and to minimise the risk of inhalation of vapours or particles. All hazardous chemicals are clearly labelled. *MP-GEN-0007 Staff Health and Safety Manual* is available for consultation by all staff.

### **5.2.4 Staff Facilities**

There is adequate access to washrooms, to a supply of drinking water to facilitate for storage of personal protective equipment and clothing.

The laboratory provides space for staff activities such as meetings and quiet study and a rest area.

### **5.2.5 Patient Sample Collection Facilities**

The Phlebotomy Department is located in the out patients department. The Phlebotomy facilities are designed to accommodate patients with disabilities allowing comfort and privacy, in addition to the optimization of collection conditions. Phlebotomy activities are conducted in the phlebotomy room which is segregated to ensure patient comfort and privacy. Patient facilities on the hospital

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wards and clinics ensure privacy, comfort and adequate space for the taking of blood samples.

Consideration is given to the accommodation of patient privacy, comfort and needs and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection.

Facilities at which patient sample collection procedures are performed enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination.

The sample collection facility has and maintains first aid materials for both patient and staff needs.

### **5.2.6 Facility Maintenance and Environmental Conditions**

All work areas within the Department of Pathology are kept clean and well maintained. It is the responsibility of the Chief Medical Scientist to ensure that all maintenance requirements relating to work areas are communicated to the General Manager and the Maintenance Department as required.

The laboratory monitors, controls and records environment conditions, as required by relevant specifications or where they may influence the quality of the sample, results and /or the health of the staff. Attention is paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibrations and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.

The temperature of fridges, freezers, cold rooms and the room temperature are monitored either manually or by the Rees Centron Environmental Monitoring System, as defined in *MP-GEN-0010 Management of the Rees Monitoring System*. The system records temperatures at defined intervals, alerting where temperatures detected are beyond defined limits. Any deviation is investigated as non-conformity, as described in *QP-GEN-0005 Control of Non-Conformances*.

Environmental conditions are also assessed through the Audit Procedure, as defined in *QP-GEN-0002 Evaluation and Audits*.

In the laboratory, work is carried out at designated work stations.

There is effective separation between adjacent laboratory disciplines to prevent:

- Incompatible activity operating in the one location
- Cross-contamination
- Excess noise levels

Environmental control is in place to ensure the Department of Pathology and environment is generally clean. This is described in *LP-GEN-0016 Cleaning in the Laboratory*.

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The Laboratory provides a quiet and uninterrupted work environment where it is needed. The Department of Pathology requires an environment with adequate space, conducive to quiet and uninterrupted work, and all departments are located in separate rooms within the Department of Pathology.

### 5.3 Laboratory Equipment, Reagents and Consumables

Laboratory equipment includes hardware and software of instruments, measuring systems and laboratory information systems.

Reagents include reference materials, calibrators and quality control materials, consumables media, pipette tips, glass slides etc.

#### 5.3.1 Equipment

##### 5.3.1.1 General

The Department of Pathology is furnished with all items of equipment required for the provision of service, including primary sample collection, sample preparation, sample processing, examination and storage. Equipment is procured and managed as described in *MP-GEN-0009 Procurement and Management of Equipment* and *MP-GEN-0016 Management and Review of Contracts*.

In the selection of equipment, it is endeavoured to take account of energy efficiency rating and future disposal, as outlined in *ED-GEN-0136 HSE Procurement Policy* and *MP-GEN-0017 Procurement and Management of Equipment*.

In cases where the laboratory needs to use equipment outside its permanent control, laboratory management ensures that the requirements of ISO 15189 are met.

The laboratory replaces equipment as needed to ensure the quality of examination results.

##### 5.3.1.2 Equipment Acceptance Testing

To demonstrate capability of achieving the performance required and compliance with specifications relevant to the examinations concerned, each piece of equipment and test method is validated. This includes the Installation Qualification (IQ) and Operational Qualification (OQ), to ensure that the equipment is capable of achieving the performance required upon installation and in routine use.

Equipment that was in place prior to implementation of the Quality Management System is retrospectively validated, while all new equipment is validated prior to use. This is carried out as documented in *VMP-GEN-0001 Validation Master Plan* and *LP-GEN-0009 Equipment Validation*. *LF-BT-0106 Blood Transfusion Instrument List* details all equipment in use in the Blood Bank, *LF-HAEM-0005 Haematology Instrumentation Index* details the equipment in use in the Haematology Department. *LP-BIO-0001 Operation and Maintenance of the Abbott Architect CI8200 Analyser*

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details the use of the main analyser in the Biochemistry Department. *QF-MIC-0002 Microbiology Instrumentation Index details the equipment used in the Microbiology Department.*

*VMP-GEN-0001 Validation Master Plan* outlines the strategy for establishing, implementing and maintaining an effective calibration and maintenance programme. This ensures that instruments, equipment and systems in use in the Blood Bank, Haematology and Biochemistry are maintained, calibrated and re-qualified as required, thus ensuring fitness for use and maintenance of their validated state. As part of this plan, all equipment undergoes routine calibration and preventative maintenance at a minimum every 12 months and is carried out by external suppliers.

Decommissioning of equipment will be managed as per *MP-GEN-0019 Management of Change Control* to ensure that there is an end of life check performed before taking the unit out of use. A formal decommissioning plan for the equipment/system/ process will be required at the point of decommissioning. This is implemented through the *VMP-GEN-0001 Validation Master Plan*.

Once an item of equipment has been decommissioned, the equipment file relating to it is sent to Iron Mountain for storage and retained as defined in *MP-GEN-0002 Management of Documentation, Preparation and Control*.

Each item of equipment is labelled with:

- An asset number
- A supplier label to indicate the instrument's maintenance status. This label includes the date of last Preventative Maintenance and due date for next Preventative Maintenance.
- A label to indicate the instrument's calibration status. This includes the date of calibration and due date for recalibration.

The equipment asset number and all data relating to calibration/maintenance of the item of equipment are defined on *LF-BT-0006 Biannual/Annual Maintenance Form* and *LF-BT-0005 As Required Maintenance Form*, *LF-HAEM-0005 Haematology Instrumentation Index*, *LP-BIO-0001 Operation and Maintenance of the Abbott Architect CI8200 Analyser* and *QF-MIC-0002 Microbiology Instrumentation Index details the equipment used in the Microbiology Department*.

### 5.3.1.3 Equipment Instructions for Use

Equipment may only be used by trained and authorised personnel. The operation and maintenance of each piece of equipment is detailed in the relevant standard operating procedure which is available at point of use. Standard Operating Procedures and/or user manuals define the safety precautions to be adhered to when using equipment.

In addition, current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment is readily available.

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The laboratory has procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

#### **5.3.1.4 Equipment Calibration and Metrological Traceability**

The validation of all equipment, as described in *VMP-GEN-0001 Validation Master Plan* and procedures relating to the operation and maintenance of individual pieces of equipment, ensures that equipment is stored and used in ways that prevent its contamination or deterioration.

Any item of equipment that has to be calibrated by the Medical Scientist is detailed in the relevant SOP. A print out of all calibration/correction factors are maintained and are checked for correctness after each change is made.

This procedure includes:

- a) Taking into account conditions of use and the manufacturer's instructions
- b) Recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment
- c) Verifying the required measurement accuracy and the functioning of the measuring system at defined intervals
- d) Recording the calibration status and date of recalibration
- e) Ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated
- f) Safeguards to prevent adjustments or tampering that might invalidate examination results

#### **5.3.1.5 Equipment Maintenance and Repair**

The Department of Pathology has a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions and the details are recorded on LF-BT-0006 Biannual/Annual Maintenance Form, *LF-HAEM-0005 Haematology Instrumentation Index*, *QF-MIC-0002 Microbiology Instrumentation Index* details the equipment used in the Microbiology Department and in the case of the analyser in the Biochemistry records are stored in *Q-Pulse*.

Equipment is maintained in a safe working condition through regular maintenance and calibration. Equipment maintenance includes examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, are used.

When equipment is found to be defective, it is taken out of service, clearly labelled as out of order and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria. A *MF-GEN-*

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*0051 Out of Service Equipment Form* is completed. The laboratory examines the effect of any defects on previous examinations and institutes immediate action or corrective action. These records are filed in the individual Equipment File, as described in *MP-GEN-0009 Procurement and Management of Equipment*.

The majority of pieces of equipment are stationary, however equipment such as centrifuges which may be transported for repair or service are packaged and transported according to manufacturer's instructions, with decontamination documented on *MF-GEN-0037 Decontamination Declaration Form*.

Where defective equipment is to be returned for service or repair, to be serviced or repaired onsite or to be decommissioned, the instrument is cleaned as appropriate and *MF-GEN-0037 Decontamination Declaration Form* is completed as described in *MP-GEN-0009 Procurement and Management of Equipment*. A copy of *MF-GEN-0037 Decontamination Declaration Form* is retained in the equipment file.

The service engineer is given the completed *LF-GEN-0037 Decontamination Declaration Form* on arrival, is provided with adequate space for performing repairs and is provided with a laboratory coat and disposable gloves, as required.

When equipment is removed from the direct control of the Department of Pathology to be serviced or repaired, or is serviced or repaired on-site, the Department ensures that the equipment is checked and shown to be functioning satisfactorily before being returned to use, as described in *MP-GEN-0009 Procurement and Management of Equipment*. This is done by carrying out quality control testing, or maintenance/validation checks appropriate to the instrument, as described in the standard operating procedure relevant to the piece of equipment.

#### **5.3.1.6 Equipment Adverse Incident Reporting**

Adverse incidents and accidents that can be attributed directly to specific equipment is investigated and reported to the manufacturer and appropriate authorities as required. Where equipment is found to be defective, the incident is reported as a non-conformance and the effect of the defect on previous examinations is investigated, as described in *QP-GEN-0005 Control of Non-Conformances*.

Equipment is labelled to indicate the status of calibration and maintenance and the dates that recalibration and maintenance are due.

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#### **5.3.1.7 Equipment Records**

Records are maintained for each item of equipment that contributes to the performance of examinations. These equipment records includes, but not limited to the following:

- a) Identity of the Equipment
- b) Manufacturer's Name, Model and Serial Number or other Unique Identification
- c) Contact Information for the Supplier or the Manufacturer
- d) Date of Receiving and Date of Entering into Service
- e) Location
- f) Condition when Received [e.g. new, used or reconditioned]
- g) Manufacturer's Instructions
- h) Records that Confirmed the Equipment's Initial Acceptability for Use when Equipment is Incorporated in the Laboratory
- i) Maintenance Carried Out and the Schedule for Preventive Maintenance
- j) Equipment Performance Records that Confirm the Equipment's Ongoing Acceptability for Use
- k) Damage to, or Malfunction, Modification or Repair of the Equipment

These records are maintained and are readily available for the lifespan of the equipment and up to 30 years in storage.



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Table 6 - *Equipment Records* outlines the records maintained for equipment and their location.

**Table 6: *Equipment Records***

<b>Record ID</b>	<b>Record Description</b>	<b>Record Location</b>
a.	Identity of equipment	Asset Number label is located on each piece of equipment. <i>LF-BT-0106 Instrument List for Blood Transfusion</i> <i>LF-HAEM-0005 Haematology Instrumentation Index and in the case of Biochemistry they are stored on Q-Pulse.</i>
b.	Manufacturer's name, equipment type, make, model and serial number.	<i>Equipment Module in Q-Pulse and Equipment file</i>
c.	Manufacturer's contact person and telephone number.	Equipment file.
d.	Date of receipt and putting into service.	Equipment file.
e.	Current location.	<i>LF-BT-0106 Instrument List for Blood Transfusion</i> <i>LF-HAEM-0005 Haematology Instrumentation Index and in the case of Biochemistry they are stored on Q-Pulse.</i>
f.	Conditions when received e.g. new, used or reconditioned.	Equipment file.
g.	Manufacturer's instructions/manual	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
i.	Maintenance carried out and planned for the future	Preventative Maintenance of Equipment – Equipment file Future calibration and maintenance plan in <i>LF-BT-0006 Biannual/Annual Maintenance Form</i> <i>LF-HAEM-0005 Haematology Instrumentation Index and in the case of Biochemistry they are stored on Q-Pulse</i>
j.	Damage, malfunction, modification and repair	Equipment file.
k.	Predicted replacement date	Replacement date requirements for Equipment are identified in the <i>LF-BT-0005 As Required Maintenance Form</i> . Expiry dates of reagents and products are indicated on the label of the product.

It is the responsibility of the Quality Co-ordinator and the Chief Medical Scientist to ensure that all the relevant documentation is obtained and maintained for each piece of equipment.

It is also the responsibility of the Quality Co-ordinator and Chief Medical Scientist to ensure that validation, calibration and maintenance are kept up to date and carried out in accordance with the relevant plan. This activity is aided through the use of *LF-BT-0006 Biannual/Annual Maintenance Form*, *LF-HAEM-0005 Haematology Instrumentation Index*, *QF-MIC-0002 Microbiology Instrumentation Index* details the equipment used in the *Microbiology Department* and in the case of Biochemistry they are stored on Q-Pulse

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### 5.3.2 Reagents and Consumables

#### 5.3.2.1 General

- The Department of Pathology has documented procedures for the reception, storage, acceptance testing and inventory management of reagents and consumables. All reagents and consumables undergo Quality Assurance testing prior to use in examinations. This is implemented through the procedure for batch acceptance of reagents *MP-GEN-0013 Management of Materials*. *LP-HAEM-0012 Batch Acceptance of Reagents in Haematology*, *LP-BIO-0007 Batch Acceptance of Reagents, Calibrators, Q.C. and Consumables* and *LP-MIC-0065 Batch Acceptance in Microbiology*.

#### 5.3.2.2 Reagents and Consumables – Reception and Storage

The laboratory is the sole receiving facility for reagents and consumables and it has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.

The laboratory stores received reagents and consumables according to the manufacturer's specifications.

#### 5.3.2.3 Reagents and Consumables – Acceptance Testing

Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment is verified for performance before use in examinations as per *MP-GEN-0013 Management of Materials*.

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

#### 5.3.2.4 Reagents and Consumables – Inventory Management

The laboratory has inventory control systems for reagents and consumables.

The systems for inventory control segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use as per *MP-GEN-0013 Management of Materials*.

#### 5.3.2.5 Reagents and Consumables – Instructions for Use

Instructions for the use of reagents and consumables, including those provided by the manufacturers are available to staff as required.

#### 5.3.2.6 Reagents and Consumables – Adverse Incident Reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables are investigated and reported to the manufacturer and appropriate authorities, as required in accordance with *QP-GEN-0008 Complaints Procedure*.

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### **5.3.2.7 Reagents and Consumables – Records**

Records are maintained for each reagent and consumable that contributes to the performance of examinations as per *LP-BT-0002 Monitoring of Materials in Blood Transfusion*, *LP-HAEM-0012 Batch Acceptance of Reagents in Haematology*, *LP-BIO-0007 Batch Acceptance of Reagents, Calibrators, Q.C. and Consumables* and *LP-MIC-0065 Batch Acceptance in Microbiology*.

These records include but not limited to the following:

- a) Identity of the reagent or consumable
- b) Manufacturer's name and batch code or lot number
- c) Contact information for the supplier or the manufacturer
- d) Date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service
- e) Condition when received [e.g. acceptable or damaged]
- f) Manufacturer's instructions
- g) Records that confirmed the reagent's or consumable's initial acceptance for use
- h) Performance records that confirm the reagent's or consumable's on-going acceptance for use are logged on the Internal Quality Control Logs in each department

Where the laboratory uses reagents prepared in-house, the records includes, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.

## **5.4 Pre-examination Procedures**

### **5.4.1 General**

The laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.

### **5.4.2 Information for Patients and Users**

The Department of Pathology has information available for patients and users of the laboratory services in *LP-GEN-0007 User Manual*. The information includes as appropriate:

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

#### **5.4.3 Request Form Information**

- The request forms in use in the Department of Pathology (*LF-GEN-0011 Blood Transfusion Request Form*, *LF-GEN-0019 Pathology General Request Form*, *LF-BIO-0024 Troponin-I Request Form*, *LF-BIO-0003 Gentamicin/Vancomycin Request Form*, *LF-GEN-0023 Microbiology Request Form*) are designed to capture sufficient information to identify the patient, the authorised requester as well as pertinent clinical data.

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The request forms allow spaces for the inclusion of, but not limited to, the following:

- a) Unique Identification of the Patient;
  - Forename and Surname
  - Date of Birth
  - Medical Record Number
  - Location/Address
  - Gender
- b) Name of the Requesting Clinician and Contact Details
- c) Type of primary sample and the anatomic site of origin, where appropriate
- d) Examination(s) requested
- f) Clinical relevant information about the patient for examination purposes and interpretation purposes. This includes clinical details, antibiotic therapy, and transfusion history.
- g) Date and time of primary sample collection
- h) Date and time of sample receipt
- i) Name of sample taker
- j) Date and time of receipt of samples by the Department of Pathology & Laboratory Medicine.

The format of the request form (paper) and the manner in which requests are to be communicated to the Department of Pathology are determined in discussion with the users of the service and through reviews of the *e.g Pathology Laboratory In-House Satisfaction Surveys, Pathology Laboratory General Practitioner Satisfaction Surveys*.

In exceptional circumstances, the laboratory accepts verbal requests for examinations provided the verbal request is followed up by request form.

The laboratory is willing to co-operate with users or their representatives in clarifying user's request.

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#### 5.4.4 Primary Sample Collection and Handling

##### 5.4.4.1 General

Specific instructions for the proper collection and handling of primary samples are documented in *LP-GEN-0007 User Manual* are available to all users of the service.

All hard copies of *LP-GEN-0007 User Manual* are controlled through *MP-GEN-0002 Management of Documentation, Preparation and Control*. The *LP-GEN-0007 User Manual on J drive* is updated on revision of the document.

All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, venepuncture. Patients in a hospital bed are given the opportunity to refuse.

##### 5.4.4.2 Instructions for Pre-collection Activities

The laboratory's instructions for pre-collection activities include the following:

- a) Completion of the request form or electronic request
- b) Preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients)
- c) Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives.

The current sample volumes required were determined with knowledge of sample volume requirements for manual testing and for assurance that a sample will be sufficient for further testing and investigations, e.g. antibody investigations and/or crossmatching, as required. It is not expected that required volumes will change. However, this will be reviewed periodically to ensure that neither insufficient nor excessive amounts of sample are collected.

- d) Special timing of collection, where needed
- e) Clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs)

##### 5.4.4.3 Instructions for Collection Activities

The laboratory's instructions for collection activities includes the following

- a) Determination of the identity of the patient from whom a primary sample is collected

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

#### **5.4.5 Sample Transportation**

The laboratory's instructions for post-collection activities include packaging of samples for transportation.

The laboratory has a documented procedure (*LP-GEN-0002 Specimen Transportation*) transportation of samples to ensure they are transported:

- a) Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned.
- b) Within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples.
- c) In a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

The Department of Pathology also adheres to regulations controlling the transport of samples outside the hospital including packing requirements.

Refer to *ED-GEN-0108 The European Agreement Concerning the International Carriage of Dangerous Goods by Road (UNADR)*.

#### **5.4.6 Sample Reception**

The laboratory's procedure for sample reception (*LP-GEN-0003 Specimen Reception*) ensures the following conditions are met:

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- a) Samples are unequivocally traceable, by request and labelling to an identified patient or site.
- b) Laboratory developed and documented criteria for acceptance or rejection of samples are applied.

It is the policy of the Department of Pathology to have a request form for every test requested. However, where a sample is already in the department and a verbal request is received, the testing may commence prior to receipt of the request form, as described in *LP-GEN-0007 User Manual*. The lack of a request form does not impede the processing of an urgent sample. Verbal requests for the Blood Bank are recorded on the *LF-BT-0012 Telephone Request Form*. A completed request form is requested for all additional requests in each department.

All samples received by the Department of Pathology must meet the acceptability criteria. This ensures that primary samples are traceable to an identified individual. Samples that do not meet acceptability criteria will result in a delay in processing or rejection of the sample. These are communicated to the requesting clinician or area to which the patient has presented. Rejected samples are recorded as per *LP-BT-0001 Specimen Handling in Blood Transfusion*, *LP-GEN-0003 Specimen Reception*, *LP-GEN-0014 Specimen Handling in the Blood Sciences Laboratory* and *Lp-MIC-0063 Specimen Reception in the Microbiology Laboratory*.

- c) Criteria are developed and documented for acceptance or rejection of primary samples. If the primary sample cannot be easily repeated the person responsible for the collection can present at the laboratory to label the specimen correctly and take responsibility for same. If compromised primary samples are accepted, the final report will indicate the nature of the problem and, if applicable, that caution is required when interpreting the result. This is implemented through the *LP-GEN-0007 User Manual*.

If an amendment is made, the final report indicates the nature of the problem and, where applicable, that caution is required when interpreting the result.

- d) All primary samples received are recorded/logged onto the LIS as per procedure. The date and time of receipt of samples, as well as the identity of the receiving member of staff, are recorded.
- e) Authorized personnel evaluate received samples to ensure they meet the acceptance criteria relevant for the requested examination(s).

In the Blood Bank, crossmatch requests that deviate from the *HF-GEN-0003 OLH Maximum Blood Ordering Schedule* are clarified by contacting the requesting clinician, as described in *LP-BT-0001 Specimen Handling in Blood Transfusion*. Requests for platelets, factor concentrates and plasma may be checked with the Consultant Haematologist, to verify the appropriateness of specific requests outside the *HF-GEN-0069 Major Haemorrhage Protocol*.

In the Haematology and Biochemistry Departments, requests that deviate from *LP-GEN-0014 Specimen Handling in the Blood Sciences Laboratory* are



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rejected and the details are logged on *QF-GEN-0047 Specimen Rejection/Amendment Form*.

- f) Where relevant, there are instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed.

As part of *HF-GEN-0019 Acute Massive Blood Loss* all users of the Blood Bank are advised to telephone in advance of sending urgent samples to ensure that they are received and prioritised. It is also recommended that urgent samples are hand-delivered to a Medical Scientist in the Blood Bank by the sample taker, to ensure that acceptability criteria can be checked in the presence of the sample taker to minimise delay in processing the sample.

Urgent requests received in Haematology and Biochemistry are managed in accordance with *LP-GEN-0003 Specimen Reception*.

Aliquots of samples frozen for future testing are labelled with permanent marker to include the primary sample ID number and the patient's name, date of birth and medical record number, and date of freezing, thus ensuring that sample portions are traceable to the original primary sample.

#### **5.4.7 Pre-examination Handling, Preparation and Storage**

The Department of Pathology has procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

Samples are stored for a specified time, under conditions ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations that may be requested (as long as time requirements are met). *LP-BT-0001 Specimen Handling in Blood Transfusion* and *LP-GEN-0003 Specimen Reception*, *LP-GEN-0014 Specimen Handling in the Blood Sciences Laboratory* and *LP-MIC-0063 Specimen Reception in Microbiology*.

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## **5.5 Examination Procedures**

### **5.5.1 Selection, Verification and Validation of Examination Procedures**

#### **5.5.1.1 General**

The Department of Pathology uses examination (testing) procedures, including those for selecting/taking sample portions, which meet the needs of the users and are appropriate for the examinations. The Department of Pathology uses procedures that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international, national or regional guidelines.

#### **5.5.1.2 Verification of Examination Procedures**

The Department of Pathology validates all testing procedures before being introduced into routine use as per the requirements of the *VMP-GEN-0001 Validation Master Plan for the Pathology Laboratory*. Retrospective validation is performed on existing procedures. Approved Validation Plans are used to confirm that the testing procedures are suitable for their intended use. Testing is performed as indicated in the Validation Plan. Results of all validation testing are recorded and assessed against the acceptance criteria specified in the Validation Plan. A Validation File is maintained for each test method or group of parameters that constitute the method/test examination. The identity of persons performing activities in examination processes is recorded.

Validation examination procedures used without modification are subject to independent verification by the laboratory before being introduced into routine use.

The laboratory obtains information from the manufacturer/method developer for confirming the performance characteristics of the procedure.

The independent verification by the laboratory confirms through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedures have been met. The performance claims for the examination procedure confirmed during the verification process are those relevant to the intended use of the examination results.

The laboratory documents the procedure used for the verification and records the results obtained. Staff with the appropriate authority reviews the verification results and record the review.

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### **5.5.1.3 Validation of Examination Procedures**

Validation is completed on

- b) Non-standard methods
- c) Laboratory designed and developed methods
- d) Standard methods used outside their intended scope
- e) Validated methods subsequently modified

The Department of Pathology validates examination procedures derived from Laboratory designed or developed methods as per *VMP-GEN-0001 Validation Master Plan for the Pathology Laboratory*.

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

Performance characteristics of the examination procedure include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision, measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity.

The laboratory documents the procedure used for the validation and record the results obtained. Staff with the authority reviews the validation results and record the review.

When changes are made to a validated examination procedure, the influence of such changes is documented and, where appropriate, a new validation is carried out.

### **5.5.1.4 Measurement Uncertainty of Measured Quantity Values**

The Department of Pathology determines the uncertainty of results, in the examination phase used to report measured quantity values on patients' samples. The laboratory defines performance requirements for the measurement of uncertainty of each measurement procedure and regularly reviews estimates of measurement uncertainty in accordance with *LP-GEN-0010 Uncertainty of Measurement*.

The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of the measured value.

It is the policy of the Department of Pathology to focus on the elimination or reduction of errors in the following critical areas of activity:

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- Sampling
- Sample preparation
- Sample portion selection
- Calibrators
- Reference materials
- Input quantities
- Equipment used
- Environmental conditions

Examples of areas of uncertainty of measurement are:

- Procedure is not defined or ambiguous
- Environmental conditions are inaccurate for storage or testing
- Incorrect sample type received
- Inaccurate dilutions
- Incorrect use of reagents
- Inadequate training of staff
- Scientific misinterpretation by staff
- Transcription errors
- Equipment systematic or random errors
- Inadequate preventative maintenance

*This list is not exhaustive*

### **5.5.2 Biological Reference Intervals or Clinical Decision Values**

The laboratory defines the biological reference intervals or clinical decision values, documents the basis for the reference intervals or decision values and communicates this information to users via the report form.

When a particular biological reference interval or decision value is no longer relevant for the population served, appropriate changes are made and communicated to the users.

When the laboratory changes an examination procedure or pre-examination procedure, the laboratory reviews associated reference intervals and clinical decision values, as applicable.

Biological reference intervals are periodically reviewed at quality meetings for their appropriateness. A review of biological reference intervals also takes place when there is a change in any pre-examination or examination procedure. All changes are managed using *MP-GEN-0019 Management of Change Control*.

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### **5.5.3 Documentation of Examination Procedures**

Examination procedures, in the form of Standard Operating Procedures (SOPs) are available at the work station where the test and examination procedures are performed.

The testing procedures are based on instructions for use from the manufacturer. All additional information required to perform the test is documented in the technical procedure for the test method(s).

Performance specifications for each procedure used in an examination relate to the intended use of that procedure. This is implemented through the relevant technical procedure.

Where summaries of information are available at a workbench for quick reference (e.g. test codes), these correspond to, and are referred to in, the relevant technical procedure. Such summaries are controlled under *MP-GEN-0002 Management of Documentation Preparation and Control*.

All test procedures are reviewed every 2 years or before that if a major amendment is required. These reviews are documented.

All test/ examination procedures are prepared as per *QP-GEN-0010 Writing a Standard Operating Procedure* and as per *MP-GEN-0002 Management of Documentation Preparation and Control* and are subject to document control. In addition to document control identifiers, documentation includes, where applicable to the examination procedure, the following:

- a) Purpose of the examination
- b) Principle and method of the procedure used for examinations
- c) Performance specifications (e.g. linearity, precision, accuracy expressed as uncertainty of measurement, detection limit, measuring interval, trueness of measurement, analytical sensitivity and analytical specificity)
- d) Type of sample (e.g. plasma, serum,)
- e) Patient preparation
- f) Type of container and additives
- g) Required equipment and reagents
- h) Environmental and safety controls
- i) Calibration procedures (metrological traceability)
- j) Procedural steps

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- k) Quality control procedures
- l) Interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions
- m) Principle of procedure for calculating results, including, where relevant, the measurement uncertainty of measured quantity values
- n) Biological reference intervals or clinical decision values
- o) Reportable interval of examination results
- p) Instructions for determining quantitative results when a result is not within the measurement interval
- q) Alert/critical values, where appropriate
- r) Laboratory clinical interpretation
- s) Potential sources of variability
- t) References

The Chief Medical Scientist is responsible for ensuring that the contents of examination procedures are complete, current and reviewed by the Consultant.

Where a change is made in the manufacturer's instructions, the reagent is checked for performance and continued suitability for intended use. This is carried out and changes to technical procedures are made as described in *MP-GEN-0019 Management of Change Control*.

All changes to test/ examination procedures are processed through the *MP-GEN-0019 Management of Change Control* and the *MP-GEN-0002 Management of Documentation Preparation and Control*.

Additional validation testing performed as required.

It is policy of the Department of Pathology to inform users in advance of change to an examination procedure such that results or their interpretations could be significantly different. The implications are explained to users by memo prior to the introduction of the change. This is implemented through the *MP-GEN-0019 Management of Change Control*.

The Department of Pathology provides users of the service with a list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements, on request. This is implemented through the *LP-GEN-0007 User Manual*.

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Reagent Logs in the Department of Pathology list all reagents in use, the revision number of the package insert of the batch in current use. Current product inserts for each reagent are retained. On receipt of reagents, the revision number of product inserts is checked to be current as part of the incoming inspection process, as described in *LP-BT-0002 Monitoring of Materials in Blood Transfusion*, *LP-HAEM-0012 Batch Acceptance of Reagents in Haematology*, *LP-BIO-0007 Batch Acceptance of Reagents, Calibrators, Q.C. and Consumables* and *LP-MIC-0065 Batch Acceptance in Microbiology*.

## **5.6 Ensuring Quality of Examination Results**

### **5.6.1 General**

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

### **5.6.2 Quality Control**

#### **5.6.2.1 General**

The Department of Pathology implements daily internal quality control (QC) systems. These QC systems verify the attainment of the intended quality of results. Results of QC testing are checked to ensure that expected results are achieved, prior to the release of test results, thus assuring the quality of test results. Results of all QC testing are logged as described in *Internal Quality Assurance* procedures. Internal QC results are reviewed regularly by the Chief Medical Scientist.

Staff are required to sign off on the *Internal Quality Assurance* procedure having read and fully understood all aspects therein. This ensures that staff members understand the Internal QC system as a basis for technical and related medical decisions.

The Department of Pathology complies with quality control processes as follows:

- a) Participate in suitable programmes of inter laboratory comparisons e.g. NEQAS, LabQuality programs.
- b) Use of suitable reference materials, certified to indicate the characterization of the material.
- c) Examine or calibrate by another procedure, where required.
- d) Document statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer e.g. certificates of analysis.

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### **5.6.2.2 Quality Control Materials**

The Department of Pathology uses quality control material that reacts to the examining system in a manner as close as possible to patient samples.

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

Use of independent third party control materials are considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

### **5.6.2.3 Quality Control Data**

The Department of Pathology has procedures to prevent the release of patient results in the event of quality control failure.

The work processes in the Department of Pathology are designed to eliminate mistakes in the process of handling samples, requests, examinations and reports. In relation to eliminating errors, processes in the Department of Pathology include:

- Performance of Confirmation Groups where a patient has no historic Blood Group on file (Blood Transfusion).
- Two person checks in the validation of results in Blood Transfusion.
- The individual signing of reports by the Medical Scientist authorising results (Blood Transfusion).
- Performance of daily Internal Quality controls for each assay in the Biochemistry and Haematology Department prior to release of results for authorisation.
- Performance of daily Internal Quality Control Procedures for Microbiology in accordance with *LP-MIC-0041 Internal Quality Control in Microbiology*.

Special attention is paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc. Best practice work practices are encouraged to ensure accuracy and to eliminate degree of manual error.

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

Quality control data is reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded.



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Statistical and non-statistical techniques for process are used wherever possible to continuously monitor examination system performance.

### **5.6.3 Inter Laboratory Comparisons**

#### **5.6.3.1 Participation**

The Department of Pathology participates in inter laboratory comparisons organized by external quality assessment schemes as per the procedures for *QP-GEN-0003 External Quality Assessment*, *LP-HAEM-0015 External Quality Control in Haematology*, *LP-BIO-0020 External Quality Control in the Biochemistry Department* and *LP-MIC-0040 External Quality Assurance in Microbiology*.

The results of external quality assessments are monitored and any failures are documented, investigated and resolved as per the non-conformance system, *QP-GEN-0005 Control of Non-Conformances*. The results of the assessments are reviewed and signed-off by the Consultant, Chief Medical Scientist and Senior Medical Scientist. In addition they are discussed at the Quality Meetings with the Consultant. A review of these results is presented at the Annual Management Review Meeting.

Inter laboratory comparison programmes are in substantial agreement with ISO/IEC 17043. External quality assessment programmes provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.

The laboratory has a documented procedure for interlaboratory comparison participation *QP-GEN-0003 External Quality Assessment* that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme.

Interlaboratory comparison programmes chosen by the laboratory do, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures and post-examination procedures, where possible.

#### **5.6.3.2 Alternative Approaches**

There are External Quality Assurance Programmes available for the tests listed on the scope of ISO 15189 accreditation in the Blood Bank and for the tests proposed for extension to scope of ISO 15189 accreditation by Haematology and Biochemistry Departments. There is no need for alternative approaches to be taken.

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### 5.6.3.3 Analysis of Interlaboratory Comparison Samples

The laboratory integrates interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.

Interlaboratory comparison samples are examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.

The laboratory does not communicate with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data.

The laboratory does not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this would be routinely done with patient samples.

### 5.6.3.4 Evaluation of Laboratory Performance

The performance in interlaboratory comparisons are reviewed and discussed with relevant staff. Final reports are discussed at the quality meetings and *QF-GEN-0042 Review of External Quality Control* is signed off by the appropriate Consultant, Chief Medical Scientist and Senior Medical Scientist.

When predetermined performance criteria are not fulfilled (i.e. non-conformances are present), staff participate in the implementation and recording of corrective action. The effectiveness of corrective action is monitored. The returned results are evaluated for trends that indicate potential non-conformances and preventive action is taken.

### 5.6.4 Comparability of Examination Results

There are defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.

The laboratory notifies users of any differences on comparability of results and discusses any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand and when examination methods are changed. This is in accordance with *MP-GEN-0001 Management of the Laboratory*.

The laboratory documents, records, and, as appropriate, expeditiously acts upon results from the comparisons performed. Problems or deficiencies identified are acted upon and records of actions retained.

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## **5.7 Post-Examination Processes**

### **5.7.1 Review of Results**

Only authorized trained personnel review the results of examinations, evaluate them in conformance with the clinical information available regarding the patient and authorize the release of the results. The procedure to be applied to the review and release of results, including urgent results is defined in individual departmental procedures.

The procedures also describe that the authorised personnel ensures review of the results of examinations before release and evaluates them against internal quality control and, as appropriate, available clinical information and previous examination results.

When the procedure for reviewing results involves automatic selection and reporting, review criteria is established, approved and documented.

### **5.7.2 Storage, Retention and Disposal of Clinical Samples**

The Blood Bank has documented procedures for the identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.

The laboratory defines the length of time, clinical samples are to be retained. Retention times are defined by the nature of the sample, the examination and any applicable requirements.

All clinical material i.e. primary samples are retained and stored in accordance with the requirements, thus ensuring the validity of a repeat examination, if required. Samples are finally disposed of in accordance with the *ED-GEN-0035 Guidelines for Management of Healthcare Waste 2010* and *MP-GEN-0007 Staff Health and Safety Manual*.

Safe disposal of samples no longer required for examination are carried out in accordance with the *ED-GEN-0035 Guidelines for Management of Healthcare Waste 2010* and *MP-GEN-0007 Staff Health and Safety Manual*.

## **5.8 Reporting of Results**

### **5.8.1 General**

There is a procedure in place to describe reporting of results in the laboratory *MP-GEN-0014 Reporting of Results*. The results of each examination are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.

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The laboratory defines the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory.

The format of reports is decided by the Chief Medical Scientist with input from Consultants, Scientific Staff and Laboratory IT Co-ordinator. Users may raise issues relating to the quality of the results report through *QF-GEN-0001 Pathology Laboratory In-House Satisfaction Survey* and *QF-GEN-0002 Pathology Laboratory General Practitioner Satisfaction Survey* which are distributed and reviewed, or the Complaints System, as described in *QP-GEN-0001 User Satisfaction*, *QP-GEN-0008 Complaints Procedure*.

The laboratory has procedures to ensure the correctness of transcription of laboratory results.

Reports include the information necessary for the interpretation of the examination results.

### **5.8.2 Report Attributes**

The Department of Pathology ensures that the following report attributes effectively communicate laboratory results and meet the users' needs:

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

### **5.8.3 Report Content**

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

- a) Clear, unambiguous identification of the examination, where appropriate the examination procedure
- b) Identification of the department which issued the report
- c) Identification of all examinations that have been performed by a referral laboratory
- d) Unique identification (Medical Record Number) and location of the patient (Hospital Ward) where possible, and destination of the report
- e) Name or unique identifier of the requester (Clinician) and the requester's contact details

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- f) Date of primary sample collection and time when available and relevant to patient care.
- g) Primary sample type.
- h) Measurement procedure, where appropriate
- i) Examination results reported in SI units, units traceable to SI units or applicable units
- j) Biological reference intervals, where applicable, clinical decision values or diagrams supporting clinical decision values, where applicable
- k) Interpretation of results, where appropriate
- l) Other comments such as cautionary or explanatory notes e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure
- m) Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available (this is rarely, if ever, applicable to this laboratory)
- n) Identification of the person reviewing the results and authorising the release of the report i.e. the individual identification of the Medical Scientist is printed on the report (if not contained in the report, readily available when needed). The initials of the Medical Scientist checking and releasing the report are recorded on the report (Blood Bank).
- o) Date of the report and time of release (if not contained in the report, readily available when needed)
- p) Page number of total number of pages (e.g. "Page 1 of 5", Page 2 of 5", etc)

The description of tests and results are presented in clear, unambiguous language, using syntax as recommended by:

- International Council for Standardisation in Haematology (ICSH)
- International Society for Blood Transfusion
- SNOMED International (College of American Pathologists)
- World Health Organisation (WHO)

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## **5.9 Release of Results**

### **5.9.1 General**

The Department of Pathology has clearly documented procedures for the release of examination results, including details of who may release results and to whom. The procedures ensure release of results to requesting clinicians/clinical areas/hospital staff only. The Laboratory policy on result reporting is that a result of an examination/test is never issued directly to patients. This is implemented through *MP-GEN-0014 Reporting of Results*.

The procedures ensure that the following conditions are met:

- a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report. The test report indicates if the quality of the primary sample received was unsuitable for examination or could have compromised the result e.g. haemolysis. It is endeavoured to check samples conformance to defined acceptability criteria as soon as possible upon receipt by the Department of Pathology. Where samples do not meet acceptability criteria, this information is entered on the LIS and is authorised immediately by a Medical Scientist to facilitate timely communication to wards. In urgent cases, this information is also telephoned to the requesting clinician.
- b) The Department of Pathology has procedures in place for immediate notification of a clinician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established “alert” or “critical” intervals. This practice also applies to results received on samples sent to referral laboratories for examination.

Records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed and any difficulties encountered in notifications.

- c) Results are legible, without mistakes in transcription and reported to persons authorized to receive and use the information.
- d) When results are transmitted as an interim report, the final report is always forwarded to the requester.
- e) There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally are followed by a written report. There are records of all oral results provided.

Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

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Copies of all in-house generated results are retained electronically on the Laboratory Information System (LIS). This ensures prompt retrieval of the information.

### **5.9.2 Automated selection and reporting of results**

The Department of Pathology does not use any system for automation and reporting of results.

### **5.9.3 Revised Reports**

When an original report is revised there are written instructions regarding the revision so that:

- a) The amended report is clearly identified as an amended report
- b) The user is made aware of the revision
- c) The amended record shows the time and date of the change and the name of the person responsible for the change. This is viewable in the audit trail and paper copy of report.
- d) The original report entries remain in the audit trail when amendments are made

This is in accordance with *MP-GEN-0014 Reporting of Results*.

## **5.10 Laboratory Information Management**

### **5.10.1 General**

There is a procedure in place to describe the Laboratory Information System (LIS) used in the *MP-GEN-0012 Management and Operation of Apex*. Work undertaken in the department is logged on Apex and reports are stored indefinitely in the system.

The laboratory has a documented procedure to ensure that the confidentiality of patient information is maintained at all times. This is described in *MP-GEN-0011 Management of Data and Information*.

The central Apex main server is located at HSE DNE Headquarters, Kells, Co. Meath and is managed by the ICT Department, Kells. The LIS database is backed up nightly at 9.00pm and the whole system is backed up weekly on Wednesday mornings at 5.30am. The back-up tapes are stored in a secure fire proof location in the HSE DNE headquarters in Kells.

### **5.10.2 Authorities and Responsibilities**

The laboratory ensures that the authorities and responsibilities for the management of the information systems are defined, including the maintenance and modification to the information system that may affect patient care. This is described in

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*MP-GEN-0012 Management and Operation of Apex, LP-HAEM-0018 Operation of APEX in the Haematology Laboratory and LP-BT-0003 Operation of Apex in Blood Transfusion, LP-MIC-0082 Microbiology Apex Procedures.*

The laboratory defines the authorities and responsibilities of all personnel who use the system, in particular those who:

- a) Access patient data and information (all staff have read and signed off “Data Protection – It’s everyone’s responsibility: An Introductory Guide for Health Service Staff) Apex access levels and general security are defined in *MP-GEN-0012 Management and Operation of Apex.*
- b) All users of the Laboratory Information System are trained to ensure competence for entering patient and examination data. Entering examination data is covered during departmental training.
- c) The procedure for the amendment of examination results is outlined in *MP-GEN-0014 Reporting of Results.*
- d) The procedure for the authorization of results is described in *MP-GEN-0014 Reporting of Results.*

### **5.10.3 Information System Management**

The systems used for the collection, processing, recording, reporting, storage or retrieval of examination data and information include:

- Apex (Laboratory Information System)
- Electronic Blood Track System
- Q-Pulse

The laboratory information system is described for the Department of Pathology and Laboratory Medicine in *MP-GEN-0012 Management and Operation of Apex, LP-HAEM-0018 Operation of APEX in the Haematology Laboratory* and in *LP-BT-0003 Operation of Apex in Blood Transfusion, LP-MIC-0082 Microbiology Apex Procedures.* Apex is supplied by CSC and was upgraded to Version 6.0 in Jan 2019.

The main functions of the LIS are as follows:

- To store patient, specimen and test details
- To identify the status of tests
- To enter results
- To store test results in relation to patient details
- To provide results enquiry options
- To generate reports and labels of results and Blood Products respectively
- To provide statistical information on laboratory throughput
- Manage in part the traceability of Blood Products



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If a procedure requires alterations to reports, the LIS transition log defines the time, date and name of person responsible for the change. An audit is maintained of reports, which have been revised. The audit trail provides details of who made the amendment(s), details of the amendment(s) and the date and time of all actions. These reports are easily retrievable and available to relevant clinical personnel. This is described in *MP-GEN-0012 Management and Operation of Apex*.

The Laboratory IT Co-ordinator and the Senior Medical Scientist manages the LIS software application. They ensure that:

- Computer software, including that built into equipment, is adequate for use in the facility
- Procedures are established and implemented for protecting the integrity of data at all times
- Computers are maintained to ensure proper functioning with environmental and operating conditions necessary for maintaining the integrity of data.
- Computer programmes and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorised persons.

Access to the LIS is password controlled and user security is set up and maintained to ensure data integrity. External access to the LIS is read-only access to authorised blood results. Haemovigilance records are stored in a password protected computer in the Haemovigilance Office.

### ***Electronic Blood Track System***

The Electronic Blood Track System is used to monitor blood product from the time it is placed in the fridge or freezer to the time of removal for use. The system consists of two major components, the Blood Track Manager and the Blood Track Courier Kiosk. The database is located on a national server in a high availability virtualised server environment in the HSE National Data Centre in Clonsaugh. The system is subject to data protection and back-up as appropriate. The use of EBTS is described in LM-BT-0015 Crossmatching using Gel Technology and HP-GEN-0002 Collection of Blood Products from the Blood Transfusion Laboratory.

### ***Q-Pulse***

Q-Pulse is a tool which comprises a series of interacting modules designed to streamline key quality management system functions. Modules in Q-Pulse include Document Management for managing a document and change control of policies and procedures; CA/PA Module for capturing and managing non-conformances and complaints; and Audit Management for planning, scheduling and reporting on the audit and verification activities. An overview of the system is described in

*MP-GEN-0018 Management and Operation of Q-Pulse.*

These systems are:

- a) Validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation. For the Apex System see *VMP-GEN-0001*

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*Validation Master Plan and IOQ-BT-0008 IOQ APEX 5.8. For the Electronic Blood Track system see PQ-BT-001 Performance Qualification Protocol for Electronic Blood Track System.*

- b) Documented and the documentation, including that for day to day functioning of the system, readily available to authorized users.
- c) Protected from unauthorized access. Access to all systems is password controlled and user security is set up and maintained to ensure data integrity.
- d) Safeguarded against tampering or loss. The requirement to provide a log on code for access, graded levels of access, audit trails and automatic logout safeguards from unauthorised adjustments or tampering that might invalidate examination results. Where adjustments are made, these are documented through *MP-GEN-0019 Management of Change Control*.
- e) Operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription.
- f) Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions.
- g) In compliance with national and international requirements regarding data protection. This is described in *MP-GEN-0011 Management of Data and Information*.

The laboratory verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory verifies that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory has a documented contingency plan to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service. This is described in *LP-GEN-0015 Laboratory Contingency Plan*.

The information systems are managed and maintained on-site and laboratory management is responsible for ensuring that the operator of the system complies with all applicable requirements of ISO 15189:2012. This is in accordance with *MP-GEN-0011 Management of Data and Information*.

## **6. APPENDICES**

Nil