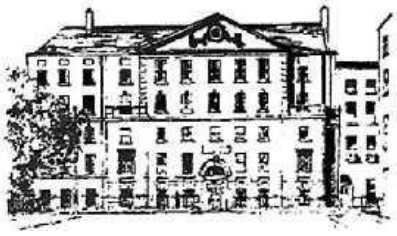

NATIONAL MATERNITY HOSPITAL
HOLLES STREET
DUBLIN 2

Department of Pathology and Laboratory Medicine

Quality Manual

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0 Introduction

0.1 Purpose and Scope

The purpose of this document is to define the policies, practices and procedures that control the effective delivery of the services provided as it relates to the Department of Pathology and Laboratory Medicine, incorporating Haemovigilance, blood component traceability, infection control and surveillance.

0.1.1 Regulations and Standards

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

1. The current version of the International Standard ISO 15189 titled "Medical Laboratories - Requirements for Quality and Competency".
2. EU Directive 2002/98/EC titled "Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components" and amending directive 2001/83/EC.
3. EU Directive 2004/33/EC Annex IV titled "Storage, Transport and Distribution Conditions for Blood and Blood Components".
4. Statutory instrument 360 of 2005 which adapts the EU Directives as defined above into Irish law.
5. AML-BB current version titled "Minimum Requirements for Blood Transfusion Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC".
6. National Standards for the Prevention and Control of Healthcare Associated Infections in Acute Health Care Services 2018.
7. Infectious Disease (Amendment) Regulations 2020 (S.I. No. 53/2020).
8. In Vitro Diagnostic Medical Devices Regulations 2022 (S.I. No. 256/2022)
9. Health and Social Care Professionals Act 2005 (Amendment Act 2020).

Therefore, this manual incorporates within the ISO 15189 framework our top level response to meeting the minimum requirements as laid out in the AML-BB and the National Standards for the Prevention and Control of Healthcare Associated Infections documents as defined above.

0.1.2 Quality Management System

Our quality management system (QMS) is based on the understanding that each individual is responsible for the quality of their contribution and that each supervisor and head of department has a responsibility to ensure that this policy is understood and followed at all times. In the event of conflict between this document and specific contracted requirements, then the latter shall take precedence.

0.2 Definitions

0.2.1 Executive Management Team

The master, secretary manager and director of midwifery and nursing.

0.2.2 Laboratory Management Team

Laboratory director, Medical consultants and laboratory manager.

0.2.3 Quality Assurance Team

Laboratory director, medical consultants, laboratory manager, quality officer, Haemovigilance officer, and medical scientists as required**.**

0.2.4 Quality Management Team

Quality officer, medical scientists with responsibility for the quality management system in each department, and Haemovigilance officer as required.

0.3 Organisation

The National Maternity Hospital (NMH), based in Holles Street, Dublin 2 has 182 beds and caters for >15,000 admissions and >48,000 outpatient events per annum. The hospital encompasses the following main activities:

1. Obstetrics and Gynaecology
2. Paediatrics
3. Surgery
4. Fetal Medicine

0.3.1 Management Structure

The management structure of the NMH and its component departments (Organisational Chart) is outlined in Appendix 6.2 of this document. The NMH comprises sub departments of Anatomical Pathology, Biochemistry, Microbiology, Haematology and Blood Transfusion. The NMH offers a 24 hour 7 days a week service in Biochemistry, Microbiology, Haematology and Blood Transfusion. Anatomical Pathology operates a 08.00-17.00 service Monday to Friday. Details of the service provided and contact details for key personnel are listed in the Primary Specimen Collection Manual (PP-CS-LM-4) and the Department of Pathology and Laboratory Medicine: Key Contacts (RF-CS-LM-23) document. Figure 1 gives a description of the services provided by the department. The services described here are designed to meet the needs and expectations of clinical personnel and patients.

Figure 1: Services of the Department of Pathology and Laboratory Medicine

Service Name	Service Description
Anatomic Pathology	The Anatomic Pathology laboratory deals with the gross and microscopic analysis of human tissue. Anatomic Pathology utilizes various techniques to process tissue and demonstrate tissue components in normal and diseased states.
Blood Transfusion	The hospital Blood Bank provides routine and emergency group and compatibility testing for obstetric, gynaecological and paediatric patients. A blood grouping service is also offered to community GP practices to support the TOP programme. The blood bank laboratory provides a stock of manufactured blood products including solvent detergent plasma, albumin and Anti-D immunoglobulin. Service is provided for intrauterine transfusion. Cord bloods are assessed for Rhesus status and Anti-D immunoglobulin issued as appropriate.
Clinical Biochemistry	The Clinical Biochemistry laboratory provides routine and emergency biochemistry testing for obstetric, gynaecological and paediatric patients.
Haematology	The Haematology laboratory provides routine and emergency haematology testing for obstetric, gynaecological and paediatric patients.
Microbiology	The Microbiology laboratory provides routine and emergency microbial identification and susceptibility testing for obstetric, gynaecological and paediatric patients. They also provide this service for the Royal Victoria Eye and Ear Hospital (RVEEH). The service for the surveillance of infectious diseases is supported.
Consultant Service	Consultant services are available for Anatomic Pathology, Biochemistry, Blood Transfusion, Haematology and Microbiology. These services are available as required 24/7 via telephone.
Haemovigilance Service	All Haemovigilance incidents are documented and reported to the National Haemovigilance Office. The Blood Bank is committed in conjunction with the Haemovigilance officer to providing a reporting mechanism that assists the quality management review process. The Consultant Haematologist is responsible for the Haemovigilance/Traceability activity. A Hospital Transfusion Committee exists that includes the following: Hospital Master Consultant Haematologist Laboratory Manager Haemovigilance Officer Director of Pathology Director of Paediatrics (or nominee) Director of Anaesthetics (or nominee) Director of Foetal Medicine (or nominee) Director of Nursing (or nominee) Chief/Senior Medical Scientist Blood Transfusion Clinical Risk Manager
Infection Control Team	The Microbiology laboratory reports all significant isolates, and diagnoses from referral laboratories in accordance with the guidelines set down by Infectious Diseases (Amendment) Regulations 2020 S.I No. 53/2020.The surveillance scientist and infection control team also reports data to the Health Protection Surveillance Centre, European Antimicrobial Resistance Surveillance Network, Antenatal HIV Reporting, the British Paediatric Surveillance Unit, the HSE and other agencies, as required. The surveillance scientist in conjunction with the Consultant Microbiologist keeps a record of all infections reported in the laboratory. The hospital Infection Control Team (ICT) includes the following: Consultant Microbiologist Surveillance Scientist Infection Control Midwife Specialist Antimicrobial Pharmacist The ICT reports to the multi-disciplinary infection control committee, chaired by the secretary/manager.

1 The Quality Policy of the Department of Pathology and Laboratory Medicine at the National Maternity Hospital

The Department of Pathology and Laboratory Medicine is committed to promoting and providing the highest quality diagnostic and consultative services for all its users. The department is committed to the implementation of the National Maternity Hospital mission statement.

The quality policy is implemented by the following means:

1. Implementation of a quality management system, the purpose of which is to review and continuously improve the quality of the services provided.
2. Setting quality objectives and plans to implement the quality policy and ensure it is appropriate to the purpose of the hospital.
3. Ensuring that all staff are familiar with the quality policy through publication of the quality manual to ensure user satisfaction.
4. Treating health and safety as a prime focus for both staff and visitors.
5. Upholding professional values and good professional practice.
6. Complying with all environmental legislation

The department will comply with the standards set by International standard ISO 15189, AML-BB, EU Directive 2002/98/EC, HIQA and INAB for the services and tests defined in the quality manual and is committed to:

1. Staff recruitment, training and development at all levels to provide an effective and efficient service to its users.
2. Providing and managing resources to ensure that laboratory examinations are processed to produce the highest quality results possible and fit for intended use.
3. Reporting results in ways, which are timely, confidential, accurate and are supported by clinical advice and interpretation when required.
4. Implementation of internal quality control, external quality assessment, audit and assessment of user satisfaction to continuously improve the quality of the service
5. The safe testing, distribution and transfusion of blood and blood components

Approved by:

_____ Date: _____/_____/_____
Dr Eoghan Mooney
Consultant Director

_____ Date: _____/_____/_____
Dr Susan Knowles
Consultant Director

_____ Date: _____/_____/_____
Dr Paul Downey
Consultant Director

_____ Date: _____/_____/_____
Mr Damian Lally
Laboratory Manager

2 Reference Documents

2.1 References Used

International Standard "ISO 15189" (current version) titled "Medical Laboratories – Requirements for Quality and Competence".

2.1.1 Master Lists

Current master lists of controlled documentation are maintained electronically on Q-Pulse. These master lists constitute the department standard operating procedures, policies, guidelines, external books/guidelines/legislative documents and relevant and traceable standards, specifications and forms.

3 Q-Pulse

Q-Pulse® version 7.0.0.190 is a compliance management system and is in place at the NMH as an enterprise response tool for compliance with the QMS and ISO 15189 management requirements.

4 Management Requirements

4.1 Organisation and Management Responsibility

1. Full name and address: Department of Pathology and Laboratory Medicine, National Maternity Hospital, Holles Street, Dublin 2.
2. Telephone: 01 637 3531
3. Fax: 01 676 5048
4. Company Registration: 0052069G
5. E-mail: dlally@nmh.ie

The laboratory is committed to performing its activities in accordance with the requirements of international standard ISO 15189 (current version). The scope of accreditation to ISO 15189 is controlled by INAB and displayed on their website www.inab.ie**.**

4.1.1 Legal Entity

All activities are carried out in the permanent facility of the NMH. The legal entity is the National Maternity Hospital, Holles St, governed by the board of governors and is legally responsible for its activities. Company registration is 0052069G.

4.1.2 Ethical Conduct

Laboratory Management ensure:

a) That there is no involvement in any activities that would diminish the confidence in the laboratory's competence, impartiality, judgement or operational integrity.
b) That management and personnel are free for any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work.
c) That where potential conflicts in competing interests may exist, they shall be openly and appropriately declared.
d) That there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements. Staff are required to adhere to ethical guidelines pertinent to their regulated status.
e) That confidentiality of information is maintained. The hospital policies with regard to patient confidentiality are strictly adhered to. Each employee is contractually bound

to desist from divulging any patient information. Any breaches of this policy will be fully investigated and appropriate censure will be taken.

f) That hospital procedures relating to The Data Protection Act 2018 are followed.
g) That all professionals adhere to the Code of Professional Conduct and Ethics set by their regulator.

This is achieved by ensuring that the hospital's Confidentiality Policy, PP-HR-GEN-8, is signed as part of the contract of all new employees. The form RF-CS-LM-85, Ethical Conduct, is distributed to all staff annually. The Laboratory Procedure Management of Data and Information, MP-GEN-DATAMAN, Section 2 also contains information on Patient Confidentiality and the Data Protection Act 2018. This document is read by all laboratory staff. See the department of pathology and laboratory medicine staff orientation and induction form, RF-CS-LM-45. Where research is being undertaken an application must be made to Pathology management who will consider if a full application for ethical approval is required. RF-CS-LM-45 also ensures that PP-CS-LM-2, Management of Research Studies: Specimens and Data, is read and acknowledged by all laboratory staff. The laboratory procedure on selection purchasing and management of equipment, MP-GEN-EQUIPMAN, outlines that it is the responsibility of all parties involved in procurement of the provision of services, to openly and appropriately declare where potential conflicts in competing interests may exist.

4.1.3 Laboratory Director

For the purpose of International Standard ISO 15189, the term Laboratory Director refers to the current chairman of the laboratory management team. This chair rotates on an annual basis between the consultant staff whose majority session commitment is to the National Maternity Hospital. The agreed term is reviewed annually and exceptions, if made, are minuted at the laboratory management meeting. See RF-CS-LM-23 for the current laboratory director.

The laboratory is thus directed by a person with the competence and delegated responsibility for the services provided. The responsibilities of the laboratory director are professional, scientific, consultative or advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory. The Laboratory Director may delegate selected duties and/or responsibilities to qualified personnel; however, the Laboratory Director has the ultimate responsibility for the overall operation and administration of the laboratory. The Laboratory Director (or their designates for delegated duties) have the necessary competence, authority and resources in order to fulfil the requirements of ISO 15189.

The Laboratory Director (or designate/s):

a) Provides effective leadership of the laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.
b) Relates and functions 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.
c) Ensures 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.
d) Ensures the implementation of the quality policy.

e) Implements a safe laboratory environment in compliance with good practice and applicable requirements.
f) Serves as a contributing member of the medical staff for those facilities served.
g) Ensures the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results.
h) Selects and monitors laboratory suppliers.
i) Selects referral laboratories and monitors the quality of their service.
j) Provides professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations.
k) Defines, implements and monitors standards of performance and quality improvement of the medical laboratory service.
l) Monitors all work performed in the laboratory to determine that clinically relevant information is being generated.
m) Addresses any complaint, request or suggestion from staff and/or users of laboratory services.
n) Designs and implements a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.
o) Plans and directs research and development, where appropriate.

4.1.4 Management Responsibility and Commitment

Laboratory management provides 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.
b) Establishing the quality policy.
c) Ensuring that quality objectives and planning are established.
d) Defining responsibilities, authorities and interrelationships of all personnel. See PP-CS-LM-13, Roles and Responsibilities, and MP-GEN-PERMAN, Personnel Management. The responsibilities, authority and inter-relationships of personnel are defined in clear terms in job descriptions. An authorised job description is available for each position within the laboratory including the Haemovigilance Officer. Each job description is approved by the Director of Pathology, Laboratory Manager, and the Human Resources Manager. The Director of Midwifery and Nursing approves job descriptions for the Haemovigilance Officer and Phlebotomists. On signing the contract of employment, personnel are accepting the job description for that position.
e) Establishing communication processes.
f) Appointing a Quality Officer. See RF-CS-LM-23, Department of Pathology and Laboratory Medicine: Key Contacts.
g) Conducting management reviews. See MP-GEN-MQA, Management of Quality Assurance.
h) Ensuring that all personnel are competent to perform their assigned activities. Training is controlled by the procedure Management of Training. MP-GEN-TRAIN, and associated documents in individual departments.
i) Ensuring availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities.

4.1.5 Needs of Users

The NMH provides services that have been designed to meet the needs of patients and clinical personnel responsible for patient care. Interpretation and advisory services are appropriate for care.

4.1.6 Quality Policy

For the purpose of ISO 15189 laboratory management have defined the intent of its QMS in a quality policy. Laboratory management shall ensure that the quality policy:

a) Is appropriate to the purpose of the organisation.
b) A statement on the laboratory's standard of service and ensuring tests are fit for intended use, to the purpose of the National Maternity Hospital. That they are in compliance with ISO 15189 and that a continual improvement of the quality of laboratory services is provided.
c) The objectives of the quality system.
d) A commitment to ensuring all personnel are familiar with and understand the organisations quality policies and objectives and implementing/ adhering to authorised procedures at all times.
e) Is reviewed for continued quality of its examinations and compliance with the quality management system.
f) The management's commitment to compliance with the International Standard ISO 15189, EU Directive 2002/98/EC, AML-BB, EU Directive 2002/98/EC, HIQA and INAB for the services and tests defined in this quality manual.

The quality policy provides a framework for establishing and reviewing quality objectives and is reviewed for continuing suitability.

4.1.7 Quality Objectives and Planning

Laboratory management have established quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the establishment. These quality objectives are measurable and consistent with the quality policy. Laboratory management ensures that planning of the QMS is carried out to meet the requirements and the quality objectives. Laboratory management ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. See procedure Management of Quality Assurance, MP-GEN-MQA), and Management of Quality Objectives, RF-CS-LM-150.

4.1.8 Responsibility, Authority and Interrelationships

See Appendix 6.2 for organisational charts. Names and contact details are documented in the Department of Pathology and Laboratory Medicine: Key Contacts, RF-CS-LM-23.

4.1.9 Communication

Responsibilities of personnel in the laboratory are defined by formal job descriptions. Job descriptions are in place for each position. They are further described in the document Roles and Responsibilities, PP-CS-LM-13. The approved responsibilities and the contract of employment associated with each position shall be such as to identify, manage and to prevent a conflict of interest. Furthermore, the lines of communication and responsibility are clearly defined in the "Organisational Chart"; refer to Appendix 6.2 of this manual. All personnel shall follow these lines of communication and authority without exception.

Communication processes are established and maintained through a series of meetings held. Reports are circulated to Clinical Governance as appropriate. Details of the meetings are outlined in Management of Quality Assurance, MP-GEN-MQA.

4.1.10 Quality Officer

Laboratory management appoints a Quality Officer who has, irrespective of other responsibilities, delegated responsibility and authority that includes:

a) Ensuring that processes needed for the quality management system are established, implemented and maintained.
b) Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives and resources, on the performance of the quality management system and any need for improvement.
c) Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organisation.

4.2 Quality Management System

4.2.1 General Requirements

Laboratory management have established a QMS that is defined in its totality by the procedures it operates to control processes which meet the defined policies and are compatible with the ethos at the National Maternity Hospital. Laboratory management ensures that all relevant personnel understand the documented policies, processes and procedures and are committed to continually monitoring and evaluating the effectiveness of the QMS in accordance with ISO 15189. The QMS provides for the integration of all processes required to fulfil the quality policy and objectives. In addition, the QMS meet the needs and requirements of the users.

The sequence and interaction of the QMS is defined by the master list of documents including the traceability and Haemovigilance activities. Key QMS processes and their interaction are defined in Appendix 6.1 titled "Pathology Department Quality Assurance Process Flow". These key elements are controlled by the management procedures in Q-Pulse. Routine maintenance of the QMS by the Quality Officer ensures that the operation and control of these processes are effective.

Fundamental to our QMS is laboratory management's commitment to ensuring procedures and programmes are in place which are regularly monitored and demonstrate function of the QMS. Laboratory management is responsible for providing the necessary resources and information (human, material, equipment) to meet the requirements to support the operation and monitoring of the QMS. Laboratory management will implement actions necessary to achieve planned results and continual improvement of these processes.

4.2.2 Documentation Requirements

The QMS documentation includes:

a) A quality policy with quality objectives. The department quality policies and objectives are clearly defined in the quality policy. The quality policy, PP-CS-LM-1, is approved by the Laboratory Director and the Laboratory Manager. The policy is framed and wall mounted at entries to the laboratory areas and phlebotomy waiting room. All laboratory and Haemovigilance staff are trained in, and are familiar with, the quality policy statement.
b) A quality manual, QM-CS-LM-1.
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. Details of such records are contained in the procedure Management of Process and Quality Records, MP-GEN-RECCON.

4.2.3 Quality Manual

This quality manual defines and describes the QMS and the structure of the documentation including Haemovigilance/Traceability. The hierarchy of the documentation system is described in Figure 3. All NMH staff will have access to the manual electronically through Q-Pulse. All staff in the laboratory are electronically distributed this manual and acknowledge that they have received it through Q-Pulse. This quality manual is formatted to correlate with the ISO 15189 standard. Key areas are addressed as outlined in Figure 2.

Figure 2: Cross-Reference of Key Elements of the Quality Manual

Key Element	Section of Quality Manual	Management Procedure	Responsibility
Introduction	0		
Description of laboratory	0.1		
Quality Policy	1	Quality Policy	Laboratory Management
Staff Education and Training	5.1	Personnel Management Management of Training	Laboratory Management. Heads of department.
Quality Assurance	4.3 to 4.15 5.1 to 5.9	Assuring Quality of Examination Procedures Internal Audit of Quality Management System Management and Review of Contracts Management of Quality Assurance Management of Process and Quality Records Review and Release of Results	Laboratory Management. Heads of department. Quality Officer.
Document Control	4.3	Document Preparation and Control	Quality Officer
Records Maintenance and Archiving	4.13	Management of Process and Quality Records	Laboratory Management. Heads of department.
Accommodation and Environment	5.2		Laboratory Management. Heads of department.
Instrument, Reagents Equipment and Consumables Management	4.6 and 5.3	Selection purchasing and management of equipment	Laboratory Management. Heads of department.
Validation of Examination Procedures	5.5	Validation of Equipment and Methods in the Laboratory	Laboratory Management. Heads of department.
Safety	5.2	Pathology Safety Statement	All Laboratory staff.

Environmental Aspects	5.2	Healthcare Risk Waste Segregation, Transport and Storage Healthcare Non Risk Waste Segregation, Disposal, Transport and Storage Hazardous Waste	All Laboratory staff.
Research		Management of Research Studies: Specimens and Data	All Laboratory staff.
Examination Processes	5.5	Assuring Quality of Examination Procedures	All Laboratory staff.
Request Protocols, Primary Specimen Collection and Handling	5.4	Primary Specimen Collection Manual	All Laboratory staff.
Validation of Results	5.6 – 5.9	Review and Release of Results	All Laboratory scientific staff.
Quality Control	5.6	Assuring Quality of Examination Procedures	All Laboratory scientific staff.
Laboratory Information Management	5.10	General Use of Winpath	All Laboratory staff.
Reporting of Results	5.8 -- 5.9	Review and Release of Results	All Laboratory scientific staff.
Remedial Actions and Handling of Complaints	4.8 – 4.12	Management of Quality Assurance	Laboratory Management. Heads of department.
Communication with Users and Suppliers	4.4	Management and Review of Contracts Primary Specimen Collection Manual	Laboratory Management. Heads of department.
Internal Audits	4.14	Internal Audit of Quality Management System.	Laboratory Management. Quality Officer.
Ethics	4.1.2	Management of Research Studies: Specimens and Data. Selection purchasing and management of equipment. Management of Data and Information.	All Laboratory staff.

The NMH quality manual includes:

a) The quality policy.

b) A description of the scope of the quality management system.

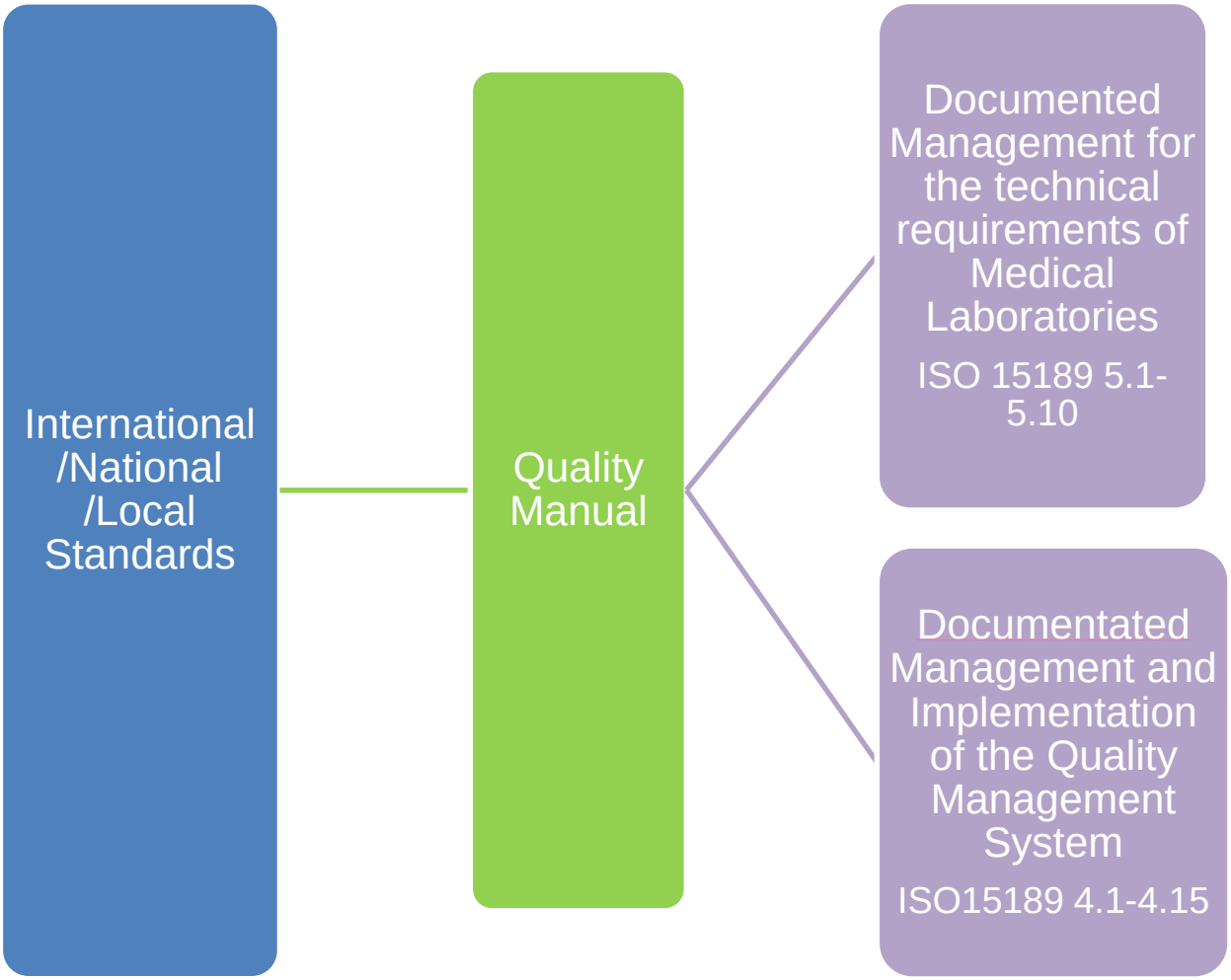
c) A presentation of the organisation and management structure of the laboratory and its place in any parent organisation. See Appendix 6.2.

d) A description of the roles and responsibilities of laboratory management (including the Laboratory Director and Quality Officer) for ensuring compliance with ISO 15189.

e) A description of the structure and relationships of the documentation used in the QMS.

f) The documented policies established for the QMS and reference to the managerial and technical activities that support them.

Figure 3: Documentation Hierarchy



4.3 Document Control

Q-Pulse is used to manage the document control cycle and provides immediate access to the documents that comprise the quality management system. To ensure that only approved and the most recent revision of documents is in place, only controlled versions of documents are in use. Approved documents are located in the active register of Q-Pulse. The procedure PP-CS-LM-16 controls all documents and information (from internal and external sources) that form part of the laboratory's quality documentation including Haemovigilance/ traceability. All approved documents, which are embedded in Q-Pulse, are controlled and cannot be changed unless a new revision is requested.

Procedures PP-CS-LM-16 and MP-GEN-RECCON ensure:

a) All documents issued to laboratory personnel as part of the QMS are reviewed and approved by approved personnel prior to issue.
b) All documents include:
    i. A title
    ii. A unique identifier
    iii. Date of current edition
    iv. Page number and total number of pages
    v. Authority for issue

These are included in the document headers in Q-Pulse.

c) Current authorised editions are identified on a document register or master index. The online use of Q-Pulse provides a master index of all documents for viewing and for full control of documentation.
d) Only current authorised editions are available at points of use. All documents used in the Department of Pathology and Laboratory Medicine are stored and accessed electronically as per MP-GEN-RECCON.
e) Hand amendments are not permitted. Any minor changes to the document are tracked through change requests as per PP-CS-LM-16. Where major modifications are required before the review date a new revision should be drafted, approved and issued. The issue, revision and approval of document control procedures are the responsibility of the Quality Officer.
f) Changes to documents are identified.
g) Documents are legible.
h) They are reviewed and updated at a frequency that ensures they remain fit for purpose. Documents are reviewed for adequacy every three years or as required to ensure that they comply with current policies and procedures. The Quality Manual, The Primary Sampling Manual and the Ethical Conduct form are exceptions with annual review. All revisions are approved prior to implementation.
i) Retained or archived superseded master documents are transferred to the obsolete register of Q-Pulse. Obsolete versions of documents are removed automatically from the point of use when the revised version is being implemented. Printed obsolete copies of document types are destroyed

4.3.1 Document Types

Documents are structured in Q-Pulse to facilitate online viewing. The Department of Pathology and Laboratory Medicine is classified under care services within the hospital document management system. The QMS documents are divided as follows:

Figure 4: Document Types

Document Type	Prefix
External Documents	EXT-CS
Patient Information	PI-CS
Policies and Procedures	PP-CS
Quality Manual	QM-CS
Records and Forms	RF-CS
Staff Information	SI-CS
Staff Memo	SI-MEM
Work Instructions	WI-CS
Safety Data Sheets	SDS-LAB

Within these document types there may be subdivisions by department as follows:

Figure 5: Document Sub Types

Document Sub Type	Prefix
Anatomical Pathology	- AP -
Biochemistry	- BIO -
Blood Transfusion	-BT-
General Pathology	- LM -
Haemovigilance	- HV -
Haematology	- HAE -
Management	- LM -
Microbiology	- MIC -
Phlebotomy	- PHE -
Specimen Reception	- SR -

Note: Many documents forming part of the QMS were generated using a different numbering nomenclature. They have been reclassified based on the current types.

4.4 Service Agreements

The procedure Management of Service Agreements, Referral Laboratories and External Service and Supplies, PP-CS-LM-18, controls the establishment and review of agreements for providing medical laboratory services. Each request form accepted by the laboratory is considered an agreement. This agreement takes into account the request, the examination and the report. The laboratory services available and the information needed on the request to ensure appropriate examination and result interpretation are defined in the Primary Specimen Collection Manual, PP-CS-LM-4, and is available electronically on Q-Pulse for hospital wide information. The following conditions are met when the NMH enters into an agreement to provide medical laboratory services:

a) The requirements of the customers, users and of the provider of the laboratory services, including the examination processes used are defined and documented in the Primary Specimen Collection Manual, PP-CS-LM-4.
b) The laboratory has the capability and resources to meet the requirements. This is reviewed at the Annual Management Review (AMR).
c) Laboratory personnel have the skills and expertise necessary for the performance of the intended examinations. This is documented in the Management of Training procedure, MP-GEN-TRAIN.
d) Examination procedures selected are appropriate and able to meet the customers' needs. All examinations procedures are validated for their intended use and the identity of the persons performing the examination is recorded. Where there are changes in

existing arrangements (for new examination procedures or changes to existing examination procedures) and prior to making any change laboratory management ensures:

i. That the test method has been documented verified and approved and is comparable with the existing method and meets the manufacturer's specification.
ii. That an internal quality control programme and external quality assessment scheme is defined, documented and in place.
iii. That the laboratory has the capability in terms of method, materials, personnel, equipment and environment to meet the new or amended requirements.
iv. That from a clinical perspective the changes meet the clinical needs of the patient.

e) Customers and users are informed of deviations from the agreement that impact upon the examination results.
f) Reference is made to any work referred by the laboratory to a referral laboratory or Consultant.

4.4.1 Review of Service Agreements

The acceptance of any contract is based on the incoming inspection process, which verifies defined requirements are met as per the Specimen Reception procedure, LP-GEN-SPECREC. On rejection of a contract (failed incoming inspection), the customer is informed, by phone where possible, or in writing and a repeat specimen may be requested as per the requirements. All rejected contracts are documented on the Laboratory Information System (LIS). A report is issued with a reason for not testing. Repeat specimens may not be possible in Anatomic Pathology, and in some instances for Microbiology or with foetal sampling. Therefore, when these specimens do not meet the incoming inspection process the clinician is contacted and all efforts are made to correctly identify the specimen received. It is the responsibility of the clinician to identify the specimen and this identification confirmation process is documented in LIS.

Reviews of agreements to provide medical laboratory services include all aspects of the agreement. Records of these reviews are stored in Q-Pulse and include any changes to the agreement and any pertinent discussions. Where an agreement needs to be amended after laboratory services have commenced, the same agreement review process is be repeated and any amendments communicated to all relevant parties.

4.5 Examination by Referral Laboratories

The laboratory, with the advice of users of laboratory services is responsible for selecting the referral laboratory, referral consultants and suppliers. The NMH monitors the quality of performance and ensures that the referral laboratories, referral consultants and suppliers are competent to perform the requested examinations. The laboratory procedure on Management of Service Agreements, Referral Laboratories and External Service and Supplies, PP-CS-LM-18, outlines how the choice of referral laboratories, consultants and suppliers used by the NMH is based on one or more of the following criteria:

- Accreditation status.
- Range of tests provided.
- Reputation of Institution or individual experts.

4.5.1 Selecting and Evaluating Referral Laboratories, Referral Consultants and Suppliers

The NMH evaluate and select referral laboratories, consultants and suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratories requirements. These referral laboratories, consultants and suppliers must meet the clearly defined requirements of the product/service being purchased. The basis on which the supplier is selected is recorded and may satisfy one or more of the following:

- The supplier is registered in an appropriate quality assurance system.
- The supplier is the sole supplier of a particular product.
- The supplier has a proven record of reliability without being in a quality assurance system.
- Historical evaluation based on price, quality and delivery.
- They are registered with the Health Products Regulatory Authority (HPRA).
- The supplier has achieved appropriate certification or validation.

A master list of all relevant evaluated referral laboratories, consultants and suppliers is stored in Q-Pulse. Continuous review is achieved by recording any untoward performance in the CA/PA module of Q-Pulse. In this way a continuous picture will be built up to enable an accurate evaluation of service. If a contract is amended, the contract is treated as a new contract and reviewed in the same manner. All amendments will be communicated to the relevant personnel.

4.5.2 Provision of Examination Results

The NMH (and not the referral laboratory) is responsible for ensuring that examination results of the referral laboratory are provided to the person making the request. The NMH prepares the report and includes all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report indicates which examinations were performed by a referral laboratory or Consultant. The author of any additional remarks is clearly identified.

Each laboratory has adopted the most appropriate means of reporting referral laboratory results which takes into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. Where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, this process is not hindered by commercial or financial considerations. Requests and results of all samples referred are stored as per MP-GEN-RECCON.

4.6 External Services and Supplies

PP-CS-LM-18 defines the practice for the selection, purchasing and approval of external services, equipment, reagents and consumables considered to be critical to the delivery of its service. An electronic master list of critical equipment, reagents, consumables and external services is maintained in Q-Pulse. Continuous review is achieved by recording any untoward performance in the CA/PA module of Q-Pulse. In this way a continuous picture will be built up to enable an accurate evaluation of service.

4.7 Advisory Services

The NMH provides an extensive advisory service. The contact details for all Consultants and departments are listed in the Primary Specimen Collection Manual, PP-CS-LM-4. A list of key contacts, RF-CS-LM-23, is available on Q-Pulse which lists the consultants and their

deputies. The results of all examinations are advice to clinical colleagues. Therefore the written report is advice. In addition to this advice is offered at multidisciplinary meetings and Consultant rounds/clinics where cases are discussed. The department collaborates actively with clinical colleagues, contributing to sections of the Annual Clinical Report. The following is a list of the some of the advisory services offered by the department:

1) Advise on choice of examinations and use of the service.
2) Clinical indications and limitations of examination procedures.
3) Specimen type and examination turnaround times.
4) Appropriate biological reference ranges.
5) Frequency of requesting the examination.
6) Professional judgements on the interpretation of results of examinations.
7) Advising on individual clinical cases.
8) Promotion of the effective utilisation of laboratory services.
9) Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.
10) Education of clinical and ancillary staff in laboratory medicine and Haemovigilance matters.
11) Choice of blood and blood products.
12) Management of severe haemorrhage.

All advice offered by laboratory staff follows protocols agreed by the Consultant. The National Haemovigilance Office provides advisory services for Blood Transfusion and Haemovigilance. Meetings between representatives of laboratory staff and internal hospital clinical staffs are held as outlined below. The purpose of such meetings is to ensure the best possible delivery of service. Minutes are held by the attendees as appropriate. Information from these meetings enables continual feedback to the laboratory and QMS.

Figure 6: Schedule of Meetings with Laboratory Involvement

Meeting	Attendance	Frequency
Maternal-Foetal medicine	Consultant Pathologists, Laboratory Manager, Medical Scientists.	Weekly
Neonatal	Consultant Microbiologist (as required), Consultant Haematologist, Laboratory Manager, Surveillance Scientist	Weekly
Gynaecology	Consultant Histopathologists, Laboratory Manager	Monthly
Clinico-Pathology	Consultant Pathologists, Laboratory Manager, Medical Scientists.	Fortnightly
Perinatal Morbidity and Mortality	Consultant Pathologists, Laboratory Manager, Medical Scientists	Monthly
Clinical Staff Meeting	Consultant Pathologists.	Monthly
Heads of Department	Laboratory Manager.	Monthly
Drugs & Therapeutics	Consultant Microbiologist.	Quarterly
Clinical Governance	Director of Pathology, Laboratory Manager, Haemovigilance Officer.	As required when an NC that requires laboratory input is discussed.
Clinical Governance Executive	Consultant Histopathologist, Consultant Microbiologist	Monthly
Infection Control	Consultant Microbiologist, Surveillance Scientist.	Quarterly
Transfusion Committee	Master, Consultant Haematologists, Consultant anaesthetist, Laboratory Manager, Chief / Senior Medical Scientists Blood Transfusion, Haemovigilance Officer.	Triannually
User Groups	Consultant Pathologists, Laboratory Manager, Users.	Scheduled
Quality Assurance	Consultant Pathologists, Laboratory Manager, Quality Officer, Haemovigilance Officer and Medical Scientists as required.	12 times per year/ As required
Head of Department	Laboratory Manager, Chief / Senior Medical Scientists	Monthly
Laboratory Staff Meetings	All Laboratory Staff	As required

4.8 Resolution of Complaints

The Primary Specimen Collection Manual, PP-CS-LM-4, outlines how the Department of Pathology and Laboratory Medicine handles user complaints. The laboratory will document all perceived or real grievances from clinicians, patients or other related parties and investigate as formal complaints. Complaints are dealt with in the first instance by the head of department. Records of all complaints including appropriate investigations and corrective actions taken are reviewed and maintained in Q-Pulse. The customer complaints process and outputs are reviewed at the monthly quality assurance meeting. Clinical Governance is made aware of written complaints to ensure compliance with hospital policy. Monitoring and resolution of complaints are reviewed as part of the AMR. The laboratory is committed by use of surveys to establishing a method of measuring customer satisfaction.

4.9 Identification and Control of Non-Conformities

The laboratory has documented procedures to identify and manage non conformities in any aspect of the QMS. The procedure MP-GEN-MQA ensures that:

a) The responsibilities and authorities for handling nonconformities are designated.
b) The immediate actions to be taken are defined.
c) The extent of the nonconformity is determined.
d) Examinations are halted and reports withheld as necessary.
e) The medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorised individual responsible for using the results is informed.
f) The results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified as necessary.
g) The responsibility for authorisation of the resumption of examinations is defined.
h) Each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented.

4.10 Corrective Action

The procedure MP-GEN-MQA ensures that:

a) Non conformities are documented and reviewed.
b) The root cause of the non-conformity is identified.
c) Corrective and/or preventative action is implemented if required to ensure the non - conformity does not recur.
d) The effectiveness of the corrective and/or preventative action is reviewed.

4.11 Preventative Action

The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. The procedure MP-GEN-MQA ensures that:

a) Laboratory data and information is reviewed to determine where potential nonconformities exist.
b) The root cause(s) of potential nonconformities is determined.
c) The need for preventive action to prevent the occurrence of nonconformities is evaluated.
d) The preventive action needed is determined and implemented.

e) The results of preventive action taken are recorded.
f) The effectiveness of the preventive action taken is reviewed.

The laboratory uses preventive action as a proactive process for identifying opportunities for improvement in addition to a reaction to the identification of nonconformities. Preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing). A tab has been set up on Q-Pulse allowing preventive action to be available as an individual non-conformance detail it is called "Proactive Prevention". The Proactive Prevention non-conformance contains tabs for investigation, risk analysis, preventative action, and QMT review.

4.12 Continual Improvement

The laboratory is committed to continually improving the effectiveness of the QMS, including the pre-examination, examination and post-examination processes. It does this through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy.

Improvement activities are directed at areas of highest priority based on risk assessments. Action plans for improvement are developed, documented and implemented, as appropriate. The effectiveness of the actions taken are determined through a focused review or audit of the area concerned.

Laboratory management ensures that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. Where continual improvement strategies identify opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management communicate to staff improvement plans and related goals.

Laboratory management is dedicated to the use of surveys in order to establish a method of measuring the laboratory's contribution to patient care. Where such surveys identify opportunities for improvement, laboratory management will take all necessary steps to ensure such opportunities for improvement are taken. Furthermore, laboratory management will avail of all relevant opportunities to ensure participation in hospital quality improvement activities whose objective is to improve patient care. Laboratory management is committed to continual improvement by means of providing all necessary and suitable education and training opportunities to laboratory and Haemovigilance personnel.

4.13 Control of Records

The control of quality and technical records is an essential element of the QMS. It is the intention of the laboratory management to maintain the control of records in line with current legislation, regulations and available guidelines. Records are created concurrently with the performance of each activity that affects the quality of the examination. The procedure MP-GEN-RECCON controls the identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records. All stored documents shall be clearly identified, legible and stored in such a way that they are readily retrievable and protected from unauthorised alterations. To assist legibility of completed records, all staff are trained in the completion of controlled documents. The date and, where relevant, the time of amendments on any record are captured along with the identity of the person making the amendments.

Laboratory management take all possible steps to ensure that technical records are stored in an environment that prevents damage, deterioration or unauthorised access. Storage of records shall be secure and back up made as appropriate.

Retention times for quality and technical records are defined by the Director of Pathology and Laboratory Manager. Retention times are detailed in MP-GEN-RECCON. In accordance with hospital policy, retained records may be held within the hospital or 'off site' with the hospital's preferred document management service provider. See MP-GEN-RECCON for the list of all records and their associated minimum retention times.

4.14 Evaluation and Audits

4.14.1 General

The laboratory management team has established and maintains documented procedures for planning and implementing quality audits so as to verify whether quality activities and related results conform to planned arrangements and to determine the effectiveness of the QMS. The audit process is used to continually improve the effectiveness of the QMS. All elements of ISO 15189 and AML-BB are audited on an annual basis. The schedule and scope of internal audits are pre-defined and demonstrate that pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of our users. The Quality Officer issues an annual internal audit schedule which includes audits of Haemovigilance activities and traceability by tracking blood components from receipt to transfusion.

4.14.2 Review of Requests and Suitability of Procedures and Sample Requirements

Annually at the AMR a review of the examinations provided by the laboratory is performed to ensure that they are clinically appropriate for the requests received. This review will also focus on sample volume, collection devices and preservative requirements for all sample types tested to ensure neither insufficient nor excessive amounts of samples are collected and that the sample is properly collected to preserve the analyte.

4.14.3 Assessment of User Feedback

The quality and appropriateness of the laboratories contribution to patient care is monitored and evaluated objectively. This is achieved by a combination of monitoring complaints, review of workload, assessment of new activities and through evaluation by user survey biannually. Records of user surveys are stored electronically on Q-Pulse.

4.14.4 Staff Suggestions

Staff at the NMH are encouraged to make suggestions for improvements in all aspects of the laboratory service. These suggestions are entered in Q-Pulse and are evaluated and implemented as appropriate and feedback provided to relevant staff.

4.14.5 Internal Audit

Internal audits are:

1) Planned and organised by the Quality Officer.
2) Conform to the requirements of ISO 15189 and AML-BB.
3) Performed by trained laboratory staff under the direction of the Quality Officer.
4) Are implemented according to the audit schedule and that audits are effective and maintained.
5) Scheduled such that staff do not audit of their own activities for horizontal audits.

The audit schedule takes into account the status and importance of processes, technical and management areas to be audited as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined in the relevant audit checklists.

The procedure Internal Audit of Quality Management System, MP-GEN-AUDIT, controlling this activity defines the following:

1) The responsibility and requirements for planning, conducting, reporting results and maintaining records.
2) The frequency and type of audit (vertical and horizontal).
3) Classification of nonconforming events.
4) The reporting activity.
5) Corrective actions shall be taken without delay to eliminate the causes of the detected non conformities. That follow up is performed to ensure that the stated corrective actions have been taken and that such actions are effective.
6) The mechanism for close out of nonconforming issues.
7) The documentation is traceable to the audit process. That records of this activity (audit schedule, audit checklist, audit report and audit non conformities) are maintained.
8) That the Laboratory Manager authorises audit reports.
9) That audit reports are discussed at:
    a) Department meetings
    b) Laboratory management meetings
10) That audits are reviewed and closed by laboratory management at the quality assurance meeting.

4.14.6 Risk Management

The impact of work processes and potential failures on examination results are assessed for patient safety. Where an impact has been made preventative actions are put in place to reduce or eliminate the identified risks. The decisions and actions taken are documented in Q-Pulse. This process is documented in the procedure, PP-CS-LM-23, Procedure for Risk Management in the Laboratory.

4.14.7 Quality Indicators

Quality indicators are in place to monitor and evaluate performance throughout the critical aspects of pre-examination, examination and post-examination processes. The process for implementation and monitoring of quality indicators is documented in the procedure Management of Quality Assurance, MP-GEN-MQA, and Management of Quality Objectives, RF-CS-LM-150. Quality indicators are periodically reviewed to ensure their continued appropriateness. The laboratory, in conjunction with its users, have established turnaround times appropriate to clinical needs. These are periodically reviewed.

4.14.8 Reviews by External Organisations

In response to nonconformities from external organisations the laboratory will take appropriate immediate, corrective and/or preventative actions to ensure continuing compliance with ISO 15189 and AML-BB. All records of such actions are stored in Q-Pulse.

4.15 Management Review

Laboratory management reviews the QMS annually to ensure its continuing suitability, adequacy and effectiveness and support of patient care. This review will include Haemovigilance/Traceability activities. The AMR reviews the following aspects of the laboratory:

The periodic review of requests and request forms, and suitability of procedures and sample requirements.

a) Assessment of user feedback.
b) Staff suggestions.
c) Internal audits.
d) Risk management.
e) Use of quality indicators.
f) Reviews by external organizations.
g) Results of participation in inter laboratory comparison programmes.
h) Monitoring and resolution of complaints.
i) Performance of suppliers.
j) Identification and control of nonconformities.
k) Results of continual improvement including current status of corrective actions and preventive actions.
l) Follow-up actions from previous management reviews.
m) Changes in the volume and scope of work, personnel, and premises that could affect the QMS.
n) Recommendations for improvement, including technical requirements.

The AMR analyses information for causes of nonconformities, trends and patterns that indicate process problems. The review also includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. The quality and appropriateness of the laboratory's contribution to patient care is, to the extent possible, also objectively evaluated.

4.15.1 AMR Report

The report from the AMR documents any findings, decisions made and actions taken related to:

a) Improvement of the effectiveness of the QMS and its processes.
b) Improvement of services to users.
c) Resource needs.

The AMR agenda and report are stored as a commissioned audit in Q-Pulse and available to view by all laboratory staff. Observations and actions to be taken are entered into the findings section of the audit by laboratory management. This links directly to the CA/PA module of Q-Pulse. The CAPA module is used to track and ensure that actions arising from the AMR are completed within a defined timeframe. The goals and objectives set at the previous AMR should be revisited at the next AMR so that progress versus plan can be measured. The AMR is chaired by the Director of Pathology and is attended by the:

1) Director of Pathology
2) Consultant Haematologist
3) Consultant Histopathologist(s)
4) Consultant Microbiologist
5) Consultant Biochemist
6) Laboratory Manager
7) Quality Officer
8) Chief/Senior Scientists
9) Haemovigilance Officer
10) Senior Administrative Staff

4.15.2 Day to Day Quality System Management

Regular meetings take place to manage the day to day quality system events. These meetings take place at departmental level, Quality Management Team (QMT) meetings and through the monthly Quality Assurance (QA) meetings. The purpose of these meetings is to review standard items as listed in the appropriate agendas stored in Q-Pulse. Please see RF-CS-LM-49 (QMT meeting), RF-CS-LM-51 (QA meeting), RF-CS-LM-55 (Departmental meeting).

5 Technical Requirements

5.1 Personnel

The organisational plan for the Department of Pathology and Laboratory Medicine is included in Appendix 6.3 titled “Organisational Chart”. The policy Personnel Management, MP-GEN-PERMAN, outlines all policies relating to personnel. Job descriptions define the qualifications for the post and the duties to be undertaken.

5.1.1 General

MP-GEN-PERMAN provides a documented procedure for personnel management. Records are maintained for all personnel to indicate compliance with requirements.

5.1.2 Personnel Qualifications

Laboratory management has documented records of personnel qualifications for each position. See Section 5.1.5 below. Individual qualifications reflect the appropriate education, training, experience, and competence appropriate to the position. For Consultant and scientific roles these qualifications are in accordance with those specified nationally by the HSE and/or registration bodies. It is the policy of the Department of Pathology and Laboratory Medicine that all staff making professional judgements have the applicable theoretical background and recent experience. This is achieved through employment of qualified staff and the provision of training assured by competence and proficiency programmes and participation in continuous professional development. Conferring between colleagues is promoted, and medical staffs participate in multidisciplinary meetings.

5.1.3 Job Descriptions

Job descriptions that describe the responsibilities, authorities and tasks for all personnel are out lined using the template MF-GEN-JOBDES. Job descriptions for each post are held by the Human Resource Department and the post holder. The Laboratory Manager holds electronic copies of job descriptions on their computer.

5.1.4 Personnel Introduction to the Organisational Environment

It is the policy of the NMH that all new employees, temporary or permanent, should receive induction training. We recognise that new employees need help in settling into their new environment. There are two elements to our induction process: a general hospital corporate induction programme held on a regular basis, which all new staff must attend, and an individual departmental induction process given by the Chief/Senior Scientist or designated person. Details of this induction are recorded on the Department of Pathology and Laboratory Medicine Staff Orientation and Induction form, RF-CS-LM-45.

5.1.5 Training

The Laboratory provides training for all personnel. Training is provided to staff by the Senior Medical Scientists or their designated nominees. All scientists within the department are under the supervision of a trainer until deemed competent in accordance with the

Management of Training procedure, MP-GEN-TRAIN. Training will include the following areas:

- The quality management system.
- Assigned work processes and procedures.
- The Winpath LIS.
- Health and Safety to include the prevention or containment of the effects of adverse incidents.
- Ethics.
- Confidentiality of patient information.

The effectiveness of this training programme is reviewed by competency and proficiency testing, annual review and trending of incidents.

5.1.6 Competence Assessment

Following appropriate training, the laboratory assesses the competency of each person to perform assigned managerial or technical tasks. Competence of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:

- Direct observation of routine work processes and procedures.
- 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 specially provided samples such as previously examined samples, or External Quality Assurance (EQA).
- Competency of staff in Haemovigilance activities is in the format of a questionnaire.

Retraining including proficiency assessment occurs as a corrective action following investigation of customer complaints or other non-conforming events. Retraining including proficiency assessment occurs every 18 months for staff performing emergency on-call duty.

5.1.7 Reviews of Staff Performance

In addition to the assessment of technical competence, the laboratory provides reviews of staff performance. These reviews consider the needs of the laboratory and the individual in order to maintain or improve the quality of the service given to the users. The periodic reviews are performed by staff who have received appropriate training. The reviews are conducted in accordance with the Management Performance Review form, RF-CS-LM-82.

5.1.8 Continuing Education and Professional Development

It is the policy of the Department of Pathology and Laboratory Medicine that staff take part in regular Continuing Professional Development (CPD). Specifically, the medical Consultants take part in regular professional development and participate in the Medical Council Programme for Continual Medical Development. The Medical Scientists register commenced on 31st March 2019. Medical Scientists comply with the CPD requirements as set down in the Code of Professional Conduct and Ethics. A continuing education programme is available to staff who participate in managerial and technical processes. This mandatory CPD programme has been developed by laboratory management and awards CPD points for various professional development activities. Each staff member is responsible for recording their CPD points on the CPD Tracker template, RF-CS-LM-95. Laboratory personnel are also encouraged to enrol in the CPD programme of the Academy of Clinical

and Medical Laboratory Science. Haemovigilance Officers attend development programmes organised by the National Haemovigilance Office. Records of continuous education are documented and available for review by external regulatory or accreditation bodies. Records of CPD are reviewed during performance review. Staff are encouraged to be active participants in their professional and academic bodies through participation in National and International Committees and lecturing to students.

5.1.9 Personnel Records

Records of relevant educational and professional qualifications, training and experience, and assessments of competence of all staff are maintained. These records are readily available to relevant personnel and include but are not limited to:

a) Educational and professional qualifications.
b) Copy of certification or license, when applicable.
c) Previous work experience.
d) Job descriptions.
e) Introduction of new staff to the laboratory environment.
f) Training in current job tasks.
g) Competency assessments.
h) Records of continuing education and achievements.
i) Reviews of staff performance.
j) Reports of accidents and exposure to occupational hazards.
k) Immunisation status, when relevant to assigned duties.

Some of the records listed above are not stored in the laboratory, but are in other specified locations e.g. Human Resources, Clinical Risk and Occupational Health Departments. These documents are accessible as required.

Medical staff must be on a specialist division or visiting EEA practitioner's division of the Register of Medical Practitioners. A certification or license is not required by the Laboratory Manager, Medical Scientists, Laboratory Aides or Administrative Staff in order to practice.

5.2 Accommodation and Environmental Conditions

5.2.1 General

The laboratory operates so that its workload can be performed without compromising the quality of work, quality control procedures, and safety of personnel, patients and visitors. The Director of Pathology and Laboratory Manager ensure that the accommodation and environmental conditions in the laboratory, in areas of the hospital where primary specimen collection and Point of Care Testing (POCT) under the management of the laboratory is carried out are fit for their intended use and are maintained so as to continue to be functional and reliable.

5.2.2 Laboratory and Office Facilities

The design and workflow of the laboratory and office facilities provides an environment suitable to the tasks undertaken. The following conditions are in place:

a) Access to areas affecting the quality of examinations is controlled. The Blood Sciences and Microbiology laboratories are controlled by security badge access. Access to the Anatomical Pathology laboratory is controlled via a keypad locked door with limited access. Areas not controlled by swipe card are locked when not in use.
b) Medical information, patient samples, and laboratory resources are protected from unauthorised access. All patient samples and laboratory resources are stored in the

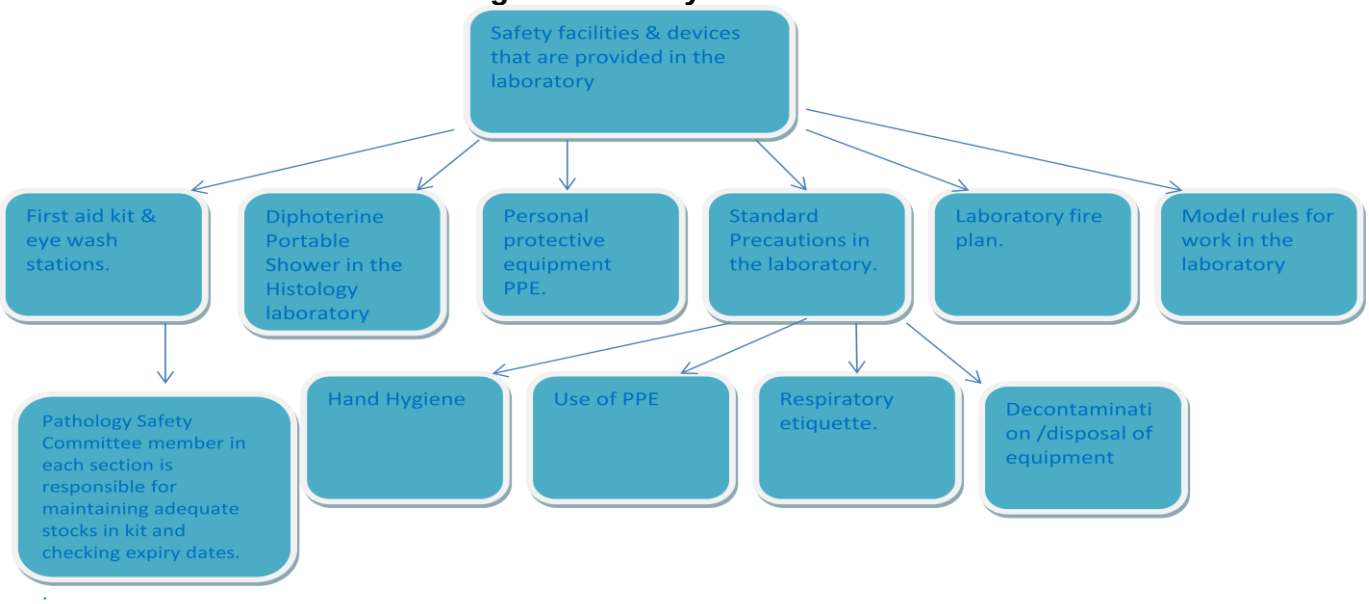
laboratory and units of the hospital that are controlled by security badge access. The exception is storage of wax blocks in the Anatomical Pathology laboratory which are stored in a locked store. Electronic medical information is stored on the LIS which is password protected, and an audit trail is available of all users who accessed all results with dates and times provided. For access to the Winpath LIS, all users are given a unique used ID/password. The Laboratory Manager approves the use of the LIS. Access to laboratory records in clinical areas is controlled by the Hospital Information Governance Policy. Electronic access in clinical areas is via password control managed by the hospital IT department.

c) Facilities for correct performance of examinations. The pathology and laboratory medicine safety statement, MP-GEN-SAFETY, outlines legislative requirements for an adequate working environment. These include: adequate power supply (including contingency), adequate lighting, adequate ventilation and temperature control, that noise and vibration do not interfere with analysis, adequate water supply, appropriate access to biological and fume cabinets, and provision for adequate disposal of biological and non-biological waste. These requirements are provided in the laboratory. It is the policy of the laboratory to monitor and control these conditions as required. Where facilities required are out of specification, then a non-conformity is completed and appropriate corrective and preventative actions taken.

d) Communication systems within the laboratory are appropriate to ensure the efficient transfer of information. Laboratory management recognises the value of good communication systems within the laboratory. This includes:
   - Standard E-mail system.
   - Laboratory meeting minutes, available on the Q-Drive once accepted.
   - Notice boards.
   - Memos.
   - Scientific updates.
   - The department has a dedicated seminar room/recreation area which provides opportunity for information sharing.

e) Safety facilities are provided and functioning regularly verified. The laboratory follows the hospitals Safety Statement which is under the remit of the Health and Safety Department. The hospital safety statement highlights the hospital managements' commitment to the safety, health and welfare. The hospital Health and Safety Department carry out annual risk assessment reviews on all areas within the hospital. These compliment Health and Safety reports submitted to the NMH Health and Safety Department by the unit managers and department heads to form the basis of the Hospital Risk Register. The pathology and laboratory medicine safety statement, MP-GEN-SAFETY, outlines the safety facilities and devices that are provided for the laboratory. See Figure 7.

Figure 7: Safety Facilities



5.2.3 Storage Facilities

Adequate storage space is provided to ensure the continuing integrity for specimens, slides, Anatomical Pathology blocks, retained micro-organisms, documents, equipment, reagents, consumables, records and results. Storage for clinical specimens is available at room temperature, vented cabinets and refrigeration at 4˚C-20˚C and -80˚C as appropriate. Computer systems are backed up each night.

There is effective separation between discrete laboratory sections, activity, and clinical samples and materials used in testing, to prevent incompatible activities operating in the one location, and cross contamination.

Storage and disposal of dangerous materials is performed in compliance with current statutory regulations and provisions.

5.2.4 Staff Facilities

Laboratory management provide access to washrooms, a supply of drinking water and to facilities for storage of Personal Protective Equipment (PPE).

The Blood Sciences laboratory contains three bathrooms. Access to fresh drinking water is provided in the Senior Room. A swipe controlled locker room for storage of PPE is located at the entrance to the lab. Two bathrooms are located in the basement where the Microbiology laboratory is located. Access to fresh drinking water is provided and there is a storage area for PPE located at the entrance to the lab. The Anatomical Pathology laboratory is located in the main hospital, with a bathroom located within the department. Access to fresh drinking water is provided, and there are lockers and a storage area for PPE located at the office area of the laboratory.

5.2.5 Patient Sample Collection Facilities

There are no patient sample collection facilities located in the laboratory. Patient sample collection facilities are located in the out-patients, semi-private, gynaecology and private clinics. These clinics encompass an area for sample collection that have:

- Separate waiting and collection areas.

- Collection areas that offer patient privacy and comfort.
- Room for an accompanying person.
- Access to disabled toilet facilities.
- Appropriate first aid materials for both patients and staff.

The specifically designated Phlebotomy facilities, within the campus, are designed specially and take into consideration patients with disabilities, providing adequate privacy. The design of the primary specimen collection facility is such to ensure the optimisation of collection as well as affording the patient every comfort.

5.2.6 Facility Maintenance and Environmental Conditions

The laboratory work areas are clean and well maintained at all times. This activity is performed in accordance with the hygiene standard requirements.

Environmental control is in place for fridges/freezers/incubators via continuous temperature monitoring so that they operate within defined specifications. The temperature is monitored by an automated system, REES Series II. This is a high security environmental monitoring system, which records temperature readings at the defined intervals under normal conditions and more frequently under alarm conditions. The system has a transaction log, which records details of when a problem occurred, who was notified and action taken. Critical areas/locations storing blood components have been temperature mapped and are re-qualified on an annual basis. Where the laboratory facilities and its environment do not meet stated or understood requirements, then such events are documented as internal service non-conformities.

The REES system is serviced annually and there is a service contract with Accuscience. A service and maintenance log is kept. There is air conditioning in the Blood Sciences and Microbiology laboratories. Down draft extraction is in place in Anatomical Pathology. Air monitoring is performed in Anatomical Pathology, records of which are kept in the Engineering and Health and Safety departments.

It is the policy of the laboratory to monitor, control and record environmental conditions as required. Where the data from such recording is out of specification then a non-conformity is completed and appropriate corrective and preventative actions taken.

Laboratory management provide a quiet and uninterrupted work environment where it is needed. In the Anatomical Pathology laboratory, there is a designated area for each Consultant Pathologist to carry out microscopy work.

5.3 Laboratory Equipment Reagents and Consumables

5.3.1 Equipment

5.3.1.1 General

The laboratory adheres to a documented procedure for the selection, purchasing, and management of equipment. Laboratory management ensures that the necessary equipment for the provision of services is available through capital and material budgetary submissions. Only equipment fit for its intended purpose is used by the laboratory. The laboratory replaces equipment as needed to ensure the quality of examination results.

5.3.1.2 Equipment Acceptance Testing

Before new equipment is put into routine use, it must have demonstrated its performance capability with respect to stated user requirements or implied or understood requirements. It is the policy of the laboratory that critical materials undergo a document check before being put to routine use. The procedure for Verification of Equipment and Methods in the Laboratory, PP-CS-LM-21, is followed to ensure that equipment is shown to function as required during routine use. This functioning is demonstrated by the use of quality control specimens and demonstrating proficiency by passing the relevant third party assessment schemes as appropriate.

Each item of equipment is uniquely labelled with an asset number and is documented on the asset register which is maintained on Q-Pulse.

5.3.1.3 Equipment Instructions for Use

Only trained personnel operate the equipment. Personnel have available (at the point of use) the relevant standard operation procedures and user manuals to operate the equipment. Refer to the document register on Q-Pulse for the master listing of relevant procedures. Standard operating procedures and or user manuals define the safety precautions to be adhered to when using equipment. Electrical safety is assured by service engineers. Storage and disposal of waste materials is performed in compliance with current statutory regulations and provisions.

5.3.1.4 Equipment Calibration and Metrological Traceability

Laboratory management establish and maintain documented procedures to control, calibrate and maintain all inspection measuring and test equipment so as to demonstrate the proper functioning of the equipment relevant to specified requirements.

a) All equipment is used taking into account the manufacturer's instructions.
b) External suppliers of calibration should be selected on the basis of accreditation status.
c) For calibration standards the metrological traceability is recorded.
d) The required measurement accuracy and functioning is confirmed via maintenance schedules, internal quality control and external quality assurance.
e) Calibration status and dates (complete and due) are recorded in the asset module of Q-Pulse or on the analyser.
f) Where calibration gives rise to a correction factor there are processes for ensuring that these are entered and confirmed as correct.
g) Safeguards are in place to ensure that only authorised staff carry out calibrations and adjust equipment.

All equipment requiring calibration is listed on the asset module of Q-Pulse. Calibration certificates are scanned and stored with the asset record. Calibration schedules are at least annual for defined equipment types. Refer to MP-GEN-EQUIPMAN, the procedure for the Selection, Purchasing and Management of Equipment. The asset module also alerts the user to the date of recalibration. The status of calibration is clearly identified on the equipment by suitable labels which identify the date of calibration, whom the calibration was performed by, and the due date of the next calibration. This process is not applicable for daily routine calibration of some analysers. Details and results of such calibrations are recorded in the equipment logs.

The Senior Medical Scientist in charge is responsible for the management of the calibration activity. They must verify that all documentation of calibration for an item of equipment, received from an external supplier is checked to ensure the equipment has passed

calibration and that the calibration is traceable. Non-conforming equipment is identified and labelled.

Decontamination procedures as appropriate are performed prior to any service or maintenance.

For examinations where metrological traceability of standard cannot be assured, certified reference materials or consensus standards/methods are used.

5.3.1.5 Equipment Maintenance and Repair

Preventative maintenance programmes are in place for equipment used for test and inspection purposes. The preventative maintenance programme will at a minimum follow the manufactures recommendations as set out in the relevant equipment manual(s). To ensure equipment is maintained in a safe working condition and in working order, service contracts are in place and maintained for critical equipment. In accordance with MP-GEN-EQUIPMAN, the procedure for Selection, Purchasing and Management of Equipment. Service contracts control calibration and preventative maintenance requirements, as outlined in the manufacturer's instructions.

The following details must be recorded for all major items of equipment:

- Dates of planned maintenance.
- Record of downtime.
- Dates when instrument decontaminated.

The above details should be recorded in the asset details of in the assets module of Q-Pulse.

When equipment is found to be defective, it is taken out of service, clearly labelled **"DO NOT USE"**, and appropriately stored until it has been shown by calibration, quality control material or otherwise to be functional. Records of such events are maintained in the assets module of Q-Pulse. Such events are documented as occurrences. In such instances corrective action requires a review to verify the validity of results traceable to the equipment in question. A non-conformance can be raised for the downtime from the asset module. See document EXT-CS-LM-3, Q-Pulse Pathology Department NMH Training Manual.

5.3.1.6 Equipment Adverse Incident Reporting

Instrument failures which result in incorrect results being reported (or near misses) are recorded and processed as per incident reporting procedures outlined in MP-GEN-MQA. Serious adverse incidents associated with instrument failure are reported to the competent authority, the HPRA. Such incidents are also reported to the hospital Clinical Governance Committee.

5.3.1.7 Equipment Records

The following records in Figure 8 are maintained for each item or similar piece of equipment used for testing purposes:

Figure 8: Equipment Records

Record ID	Record Description	Record Location
a)	Identity of equipment	Asset ID label is located on each piece of equipment. This record is also maintained on the asset module.
b)	Manufacturer's name, model and serial number.	This record is maintained on the laboratory asset module.
c)	Contact information for the supplier or manufacturer.	This record is maintained in the equipment file. A list of suppliers and contacts is maintained in Q-Pulse
d)	Date of receipt and entering into service.	This record is maintained in the equipment file and in the asset module of Q-Pulse.
e)	Current location.	This record is maintained on the laboratory asset module of Q-Pulse.
f)	Conditions when received e.g. new, used or reconditioned.	This record is maintained in the equipment file.
g)	Manufacturer's instructions/ manual	This record is maintained in the equipment file or at the point of use whichever is appropriate. All manufacturers' instructions are recorded as an external document on Q-Pulse, where available this leads to a link to an electronic copy.
h)	Records of equipment's initial acceptability for use when incorporated into lab.	Validation of equipment–Equipment file/Q-Pulse CA/PA Calibration of equipment–Equipment file/Q-Pulse Asset module QC–On equipment/ floppy/hardcopy/equipment file EQA–EQA file (hardcopy) or through the scheme website Asset module of Q-Pulse
i)	Maintenance carried out and scheduled preventative maintenance.	PM records, asset module of Q-Pulse
j)	Equipment performance records to confirm ongoing acceptance for use.	QC – On equipment/ floppy/ hardcopy EQA – EQA file (hardcopy)
k)	Damage, malfunction, modification and repair	These records are maintained in the equipment file, asset module and as non-conformities.

The procedure MP-GEN-RECCON details the retention times of the above records.

5.3.2 Reagents and Consumables

5.3.2.1 General

Each laboratory department has a documented procedure for the reception, storage, acceptance testing, and inventory management of reagents and consumables.

5.3.2.2 Reagents and Consumables - Reception and Storage

The laboratory stores received reagents and consumables according to manufacturer's instructions. Reagent and consumables are stored in designated temperature controlled environments where required. Reagents that require refrigeration or freezing are stored in reagent fridges/freezers that are temperature controlled. This is monitored by the REES temperature monitoring system. Each department has a documented procedure relating to equipment failure that provides a designated back-up fridge/freezer in the event of failure.

5.3.2.3 Reagents and Consumables - Acceptance Testing

Each new batch of examination kits with changes in reagent, procedure, lot number or consignment, has its performance verified before use. This is performed according to the documented procedure on batch acceptance in each department. Any consumables that affect the quality of examinations shall also be verified before use.

5.3.2.4 Reagents and Consumables - Inventory Management

Each department has an inventory control system for reagents and consumables. This system segregates uninspected and unacceptable reagents.

5.3.2.5 Reagents and Consumables - Instructions for Use

Current manufacturer's instructions and instructions for use, of reagents and consumables are available on Q-Pulse. External documents are recorded and given a document number. Where they are available as an electronic file they are attached in Q-Pulse, or else stored as a hard copy in the relevant department.

5.3.2.6 Reagents and Consumables - Adverse Incident Reporting

Adverse incidents and accidents associated directly with specific reagents and consumables should be recorded and processed as per incident reporting procedures outlined in MP-GEN-MQA. Serious adverse incidents associated with specific reagents and consumables are reported to the HPRA.

5.3.2.7 Reagents and Consumables - Records

The following records listed in Figure 9 are maintained for each reagent and consumable that is used for testing purposes.

Figure 9: Reagents and Consumables - Records

Record ID	Record Description	Record Location
a)	Identity of the reagent or consumable	Batch acceptance log in individual department.
b)	Manufacturer's name, batch or lot number	Batch acceptance log in individual department.
c)	Contact information for the supplier or manufacturer.	Supplier module of Q-pulse
d)	Date of receipt, expiry date, date of entering into service, and date material was taken out of service where applicable.	Batch acceptance log in individual department
e)	Conditions when received (acceptable or damaged).	Batch acceptance log in individual department
f)	Manufacturer's instructions.	This record is maintained in the equipment file or at the point of use whichever is appropriate. All manufacturers' instructions are recorded as an external document on Q-Pulse, where available this leads to a link to an electronic copy.
g)	Records to confirm reagent or consumable initial acceptability for use.	Acceptance log in individual department
h)	Performance records to confirm ongoing acceptance for use.	QC – On equipment/ floppy/ hardcopy/in equipment file EQA – EQA file (hardcopy) or on the scheme website

5.4 Pre-Examination Procedures

5.4.1 General

The laboratory has documented procedures and information for pre-examination activities, contained in the laboratory Primary Specimen Collection Manual, PP-CS-LM-4.

5.4.2 Information for Patients and Users

The laboratory has information for patients and users this is contained in the laboratory Primary Specimen Collection Manual, PP-CS-LM-4, and is available to all on the hospital intranet, at www.nmh.ie. All information stipulated in Section 5.4.2 a-n is included in this manual. The department maintains a suite of information leaflets for tests it carries out to assist patients and their families to give informed consent

5.4.3 Request Form Information

The laboratory has a suite of paper and electronic request forms. The paper request forms are available in the laboratory and are controlled in Q-Pulse. The electronic request forms are nationally agreed and are held on the MN-CMS portal.

PP-CS-LM-4 outlines the procedures to be followed for verbal requests. Laboratory staff assist users, or their representatives, to ensure clarity of requests.

The Laboratory Manager/Director of Pathology ensures where new forms or amendments to existing forms are required that prior to implementation any such changes are discussed and agreed with the relevant clinical users.

5.4.4 Primary Sample Collection and Handling

5.4.4.1 General

An approved Primary Specimen Collection Manual, PP-CS-LM-4, which records specific instructions for the proper collection and handling of primary specimens, is circulated to the primary users of the laboratory services, those responsible for sample collection whether based in the hospital or not. The manual is available on Q-Pulse and the hospital intranet.

In a situation where the user requires deviations and exclusions from, or additions to the documented collection procedure, these are recorded and included in all documents containing examination results.

All procedures carried out on a patient require informed consent**.** Consent may be given orally, in writing, and in certain limited circumstances by implication e.g. holding out an arm for a blood pressure reading. Courtesy and respect is required at all times. Consent may be verbal in emergency situations and documented in the healthcare record. In an emergency life-threatening situation where the patient is unable to consent or to appreciate what is required a healthcare professional, acting in the best interests of the patient, may administer the necessary medical treatment to save the life or preserve the health of the patient without formal consent. This exemption is limited to situations where the treatment is immediately necessary to save the life or preserve the health of the patient.

5.4.4.2 Instructions for Pre-Collection Activities

The Primary Specimen Collection Manual, PP-CS-LM-4, includes the following instructions in Figure 10 for pre-collection activities:

Figure 10: Instructions for Pre-Collection Activities

Record ID	Instructions for Pre-Collection Activities:
a	Completion of the request form (paper or electronic)
b	Preparation of the patient
c	Type and amount of primary specimen to be collected
d	Special timing of collection
e	Relevant clinical information

5.4.4.3 Instructions for Collection Activities

The Primary Specimen Collection Manual, PP-CS-LM-4, includes the following instructions in Figure 11 for collection activities:

Figure 11: Instructions for Collection Activities

Record ID	Instructions for collection activities:
a	Positive identification of the patient prior to specimen collection
b	Verification that patient meets pre-examination requirements
c	Instruction for collection of primary samples, including sample containers and any necessary additives
d	Instructions for labelling samples
e	Recording the identity of personnel collecting the specimen, collection date and time
f	Instructions for storage conditions before delivery to laboratory
g	Safe disposal of materials used in the primary specimen collection

5.4.5 Sample Transportation

The laboratory monitors and ensures by appropriate means that specimens are transported to the laboratory in such a way that the validity of the test results is not compromised. This is accomplished by the following:

a) The Primary Specimen Collection Manual, PP-CS-LM-4, clearly identifies any special time related requirements associated with specific tests to the user. Before testing the laboratory verifies these requirements are complied with.
b) The Primary Specimen Collection Manual, PP-CS-LM-4, under the special requirements section, clearly identifies any specific temperature requirements associated with preserving the integrity of specific test parameters. Before testing the laboratory verifies these requirements are complied with.
c) Adherence to regulations controlling transport of specimens. Refer to “The European Agreement Concerning the International Carriage of Dangerous Goods by Road (UNADR)”, EXT-CS-LM-10.

The Primary Specimen Collection Manual, PP-CS-LM-4, defines for the users of laboratory services, requirements for specimen delivery from within and outside the hospital.

5.4.6 Sample Reception

The laboratory has a procedure for Sample Reception, LP-GEN-SPECREC, which ensures that the following documented conditions are met:

a) Samples must be traceable by request and labelling to an identified patient or site.
b) The laboratory policy on acceptance or rejection of samples is applied. Where the specific requirements of the incoming inspection process for specimens and forms are not met for key indicators, the specimen is rejected and a second specimen is requested.
c) In general a practice of “Zero Tolerance Policy” is in place for essential details and where a discrepancy is identified, in labelling, sample instability the specimen is rejected.

In situations where the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample the final report shall indicate the nature of the problem and indicate that caution is required when interpreting the result, and the form RF-CS-LM-20, Pathology Specimen Non-conformance form, completed. When these specimens do not meet the incoming inspection process the clinician is contacted and all efforts are made to correctly identify the specimen received. It is the responsibility of the clinician to identify the specimen and this identification confirmation process is documented in Winpath. All non-conforming primary specimens (even when tests are not performed) must be registered on the LIS. The electronic registration will identify the reason for rejecting the specimens and the action taken e.g. second specimen requested. The details required on specimens is located in the Primary Specimen Collection Manual, PP-CS-LM-4.

d) All specimens received into the laboratory, either during routine or out of hours, are recorded electronically on the Winpath LIS. The electronic receipt of specimens controls the following:
    a) Date/time of receipt of specimens.
    b) The tests requested and any non-conforming events.
    c) Audit trail (including who received the specimen).
e) Primary specimens and associated forms are checked on receipt by authorised personnel including Medical Scientists, Senior Anatomical Pathology Technician and Laboratory Aides to ensure they meet the criteria in place for the acceptance and rejection of primary specimens. The acceptance or rejection is based on an inspection process, where each specimen is reviewed for compliance with defined criteria as it applies to:
    a) Suitability of the request form.
    b) Labelling of the primary specimens.
    c) Quality of the specimens (age, haemolysis, lipaemia, volume etc.)
    d) A Histopathologist (Consultant or Registrar), Senior Anatomical Technician or authorised Medical Scientists will review all requests before testing is commenced.
f) The laboratory has documented procedures in place for the receipt, labelling, processing and reporting of primary specimens received by the laboratory and are marked as urgent. Where blood components/products are required urgently, where the patient has a clinically significant antibody or in emergency situations, the requesting doctor must communicate directly with the Blood Transfusion laboratory.
g) All sample portions or aliquots are labelled so that they are traceable to the original primary specimen.

5.4.7 Pre-Examination Handling, Preparation and Storage

The laboratory has procedures and facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities. Specimens from outpatient clinics received after 17:30 (Monday to Friday) may be held to the next working day for analysis following authorisation from a senior member of staff. Specimens received out of hours which do not require urgent analysis are stored in the appropriate fridge in the Blood Sciences laboratory.

The Primary Sample Collection Manual, PP-CS-LM-4, also has documented time limits for requesting additional or further tests on the primary sample. These are outlined in the section for each department.

5.5 Examination Procedures

5.5.1 Selection, Verification and Validation of Examination Procedures

5.5.1.1 General

The laboratory uses validated examination procedures (testing) which meet the needs of its users. The laboratory uses examination procedures (testing) that are in widespread use and have been published or referenced in authoritative textbooks and journals. However, certain reagent manipulations may be required appropriate for the method used. The effectiveness of these manipulations is verified using internal and external quality control procedures. The audit trail in the LIS records those who perform activities

5.5.1.2 Verification of Examination Procedures

Testing procedures or amended procedures are validated or verified as fit for purpose by the laboratory prior to being introduced into routine use. The laboratory obtains information from the manufacturer for confirming the performance characteristics of the procedure. The performance characteristics should comply with the User Requirement Specification (URS). The URS ensures that when a system or piece of equipment is selected, it will deliver the functions required, comply with applicable standards and regulations and have all the documents and records to enable successful validation to be completed.

Independent verification by the laboratory is as extensive as necessary to meet needs. It confirms that the performance claims for the test/examination procedure have been met. The laboratory documents the procedure used for verification in a validation plan, using the template RF-CS-LM-47. The validation plan is prepared and approved by the senior in charge before beginning the validation process. A validation protocol will be created to provide evidence that the system performs as intended. The protocol will include the following:

- Scope of validation.
- Selection of a validation team and a statement on the competence of the staff involved.
- Timeline for completion.
- Procedures for installation, operational and performance qualifications.
- Acceptance criteria.
- Justification.
- Performance characteristics.
- Reference documentation.
- Change control.
- Executive summary.

5.5.1.3 Validation of Examination Procedures

The laboratory validates examination procedures derived from the following sources:

- Non-standard methods.
- Laboratory designed or developed methods.
- Standard methods used outside their intended scope.
- Validated methods subsequently modified.

Each method in use in the laboratory must be fully validated by the laboratory. The validation is as extensive as required and it should confirm through the provision of evidence that the method:

- Is suitable for the intended purpose.

- Performs to an acceptable level in the laboratory, when compared to the performance claims made by the manufacturer.
- As a minimum meets the same standard as the test being replaced.

The laboratory records the results of validations and the procedures used for such validation in a validation report, using the template RF-CS-LM-48. New methods and procedures selected for use must be evaluated and found to give satisfactory results before being used for medical examinations. These evaluations are reviewed and approved by laboratory management in the report. It is also documented through raising a new Change Management (CM) event with its own identification number using the CA/PA module of Q-Pulse. This will track the outcomes in the same way as all the non-conformance events can be tracked in Q-Pulse.

When changes are made to a validated procedure the influence of the change is documented and where appropriate revalidation may be performed:

- Following repeated failed QC results.
- Following any major change, performed under change control and deemed to require revalidation/re-qualification.
- Following a major non-conformance.
- Following a complaint from users.

Such validation is not expected to be as detailed as for a full validation and may vary depending on the extent of the repair carried out or the non-conformance raised. This procedure ensures that the method is functioning satisfactorily before return to use.

5.5.1.4 Measurement Uncertainty of Measured Quantity Values

Uncertainty of measurement may be influenced by a number of factors. These should be considered during method validation. The laboratory must define the performance requirements for the measurement uncertainty of each measurement procedure. This is a key step in deciding whether a test is fit for purpose. The measurement uncertainty for each measurement procedure in the examination phase should be determined to report measured quantity values on patients' samples.

The measurement uncertainty components are those associated with the actual measurement process, starting with presentation of the sample to the measurement procedure and ending with the output of the measured value or test results. Sources that contribute to uncertainty may include sampling, specimen preparation, portion selection, calibrators, reference materials, input quantities, equipment, environment, specimen condition and operator skill. It is assessed as applicable, and recorded in the validation plan, RF-CS-LM-47, and the validation report, RF-CS-LM-48.

Measurement uncertainty values can be calculated using values obtained by measuring IQC materials under intermediate precision conditions. This allows for the varying of factors such as changing reagent or calibrator batches, or using different operators.

Reasonable efforts across each discipline are made to identify sources of uncertainty and to quantify them to establish an overall estimate of uncertainty. Estimates of measurement uncertainty are available to users on request from each department.

PP-CS-LM-21, the procedure for Validation of Equipment and Methods in the Laboratory, outlines the laboratory approach to measurement uncertainty. The laboratory reviews

estimates of measurement uncertainty on an annual basis. This is done through a scheduled annual audit of measurement uncertainty in each department. The review is recorded on the form RF-CS-LM-84 and recorded in the annual audit.

Where tests include a measurement step but do not report a measured value, the laboratory should calculate the uncertainty of the measurement step where it has use in accessing the reliability of the procedure or has an influence on the test result.

5.5.2 Biological Reference Intervals or Clinical Decision Values

Biological reference intervals are defined and documented by the laboratory in the Primary Specimen Collection Manual, PP-CS-LM-4. This information is also communicated to users on laboratory reports.

Biological reference intervals are reviewed periodically. Where the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population then an investigation is undertaken, followed if necessary, by corrective action and updated on the laboratory information system using PP-CS-LM-9, Winpath Reference Ranges.

A review of biological references intervals shall also take place if examination or pre-examination procedures are changed. Biological reference intervals are not relevant to Blood Transfusion, Anatomical Pathology and certain areas of Microbiology.

Clinical Decision Values/Reports of Critically Abnormal Results are results which are generally unexpected and which are so abnormal that they may have implications for the immediate treatment of the patient. They may indicate a life-threatening situation. Details for clinical staff on what reports will be telephoned are outlined in the Primary Specimen Collection Manual, PP-CS-LM-4. For scientific staff, each department has identified the circumstances under which results should be telephoned. This information is available in LP-GEN-TELREP, the procedure for Telephoning / Faxing of Results.

5.5.3 Documentation of Examination Procedures

Examination procedures are documented by the laboratory and are available on Q-Pulse the laboratory quality management system so that all staff in the laboratory has access to them. The appropriate documents are also distributed to each member of staff as required by those responsible for training.

Work instructions, which are condensed documents that summarise key information, are acceptable for use in the laboratory at work stations where test and examination procedures are performed. All printed copies must be on buff paper only, and the number of printed copies is referred to in the original document. All work instructions must have a full documented procedure available for reference.

All documents that are associated with the performance of a test including procedures, summary documents, product inserts are subject to document control. In addition to this documentation must include where applicable details of:

a) Purpose of the examination.
b) Principle of the procedure used for examinations.
c) Performance characteristics as appropriate e.g. accuracy and precision, detection limit, sensitivity, specificity etc.
d) Type of primary specimen (e.g. plasma, serum, urine).
e) Patient preparation.

f) Type of container and additives.
g) Required equipment and reagents.
h) Environmental safety controls /Risk assessment.
i) Calibration procedures (metrological traceability).
j) Procedural steps.
k) Quality control procedures.
l) Interferences (e.g. lipaemia, haemolysis, bilirubinaemia) and cross reactions.
m) Principle of procedure for calculating results, including uncertainty of measurement.
n) Biological reference intervals.
o) Reportable interval of patient examination results.
p) Instruction for determining result when it is not within the measurement interval.
q) Alert/ critical values, where appropriate.
r) Laboratory interpretation.
s) Potential sources of variability.
t) References.

The Laboratory Manager ensures all examination procedures are complete, current and reviewed. The laboratory Consultants/nominee provides details of current examination procedures including performance specifications etc. to clinical users on receipt of request for same.

It is the policy of the laboratory that the relevant Consultant, Laboratory Manager or nominee inform clinical users in advance of change to an examination procedure, where the change has an impact on result interpretation. Records of changes to existing test procedures are managed through the change management module of Q-Pulse. All changes to test methodologies are discussed in advance by the laboratory management committee. Such changes are referred to the appropriate hospital committee if necessary. This notification of change can be accomplished by various methods including: direct mailing, laboratory newsletters, memos, or as part of the examination report.

5.6 Ensuring Quality of Examination Procedures

5.6.1 General

The laboratory ensures the quality of examinations by performing them under defined conditions.

5.6.2 Quality Control

5.6.2.1 General

The laboratory designs quality control (QC) procedures that verify the quality of test results obtained. The approach to quality control is based on principles of in-process QC checks as well as controlling the tests. The key inputs to each process will be reviewed and signed off on a daily basis. It is the policy of the laboratory to focus on elimination or reduction of errors in the following critical areas of activity:

1) Specimen collection, inspection and registration.
2) Laboratory Information System including interfaces and data entry contingency.
3) Primary processing including centrifugation and aliquoting.
4) Testing processes (using QC specimens). All known errors in the internal QC systems are documented.

5.6.2.2 Quality Control Materials

The laboratory uses internal quality control (IQC) materials that react to the test system as closely as possible to patient samples. IQC materials are examined with a frequency that is based on the stability of the procedure being tested and the risk of harm to the patient from an erroneous result.

Concentrations of IQC materials are chosen where possible to reflect clinical decision values. Third party IQC materials are used where possible either instead of or in addition to IQC materials supplied by the manufacturer.

5.6.2.3 Quality Control Data

Each department in the laboratory documents that patient results must not be released in the event of an IQC failure. When IQC results indicate that examination results are likely to contain significant errors, the results are rejected and relevant patient samples retested after the error has been resolved. Results from patient samples analysed after the last successful quality control event are reviewed and consideration is given to the requirement to repeat where possible and the requirement to alert the clinical team if it is anticipated that the result would be significantly different.

IQC data is reviewed at regular intervals to detect trends in performance that may indicate problems in the system. If performance trends in IQC results that indicated problems are noted or if IQC failures are recorded, a non-conformance is raised in Q-Pulse and appropriate investigation into the failure is carried out. Corrective and preventative action is then implemented and reviewed by the clinical team in charge of the department concerned.

5.6.3 Interlaboratory Comparisons

5.6.3.1 Participation

Our testing laboratory participates in a range of third party external quality assessment (EQA) schemes and proficiency programmes.

The laboratory manager and/or medical consultants formally review the results of EQA schemes. The output of this review is presented at the quality assurance meeting. An overview of performance is presented at the AMR meeting (refer to Section 4.15). Failures in EQA schemes and IQC methods are documented and investigated according to MP-GEN-MQA, the procedure for Managing Quality Assurance.

The laboratory documents the procedure for participation in interlaboratory comparisons or EQA in the Managing Quality Assurance, MP-GEN-MQA, document. Each department also has a local documented procedure for dealing with specific EQA schemes in their own departments.

It is the policy of the laboratory to ensure that EQA specimens, in so far as possible, are treated as routine specimens. EQA chosen by the laboratory should as far as possible provide material to be analysed that provides clinically relevant challenges that mimic patient samples. EQA specimens go through the normal registration, pre-examination and post-examination process. EQA specimens are used to check the competency of staff.

5.6.3.2 Alternative Approaches

Where formal EQA schemes are not available, are inadequate or do not challenge the full range of the analyte, the laboratory may develop other approaches to determine the

acceptability of examination results. The laboratory may use external derived primary specimens or portions of same to verify the test method. Examples of materials that could be used include:

- Certified reference materials.
- Samples previously examined.
- Material from cell or tissue repositories.
- Exchange of samples with other laboratories.
- Control materials that are tested daily in interlaboratory comparison programmes.

5.6.3.3 Analysis of Interlaboratory Comparison Samples

It is laboratory policy to integrate EQA samples into the routine workflow in a manner that represents as much as possible the routine testing of patient specimens. EQA specimens are examined by staff who routinely test patient samples using the same procedures used in the routine testing of patient specimens. The exception to this is, that the laboratory does not refer EQA samples for confirmatory testing where required, although this would be done with routine patient samples.

The laboratory does not collaborate with other programme users regarding samples submitted for examination.

5.6.3.4 Evaluation of Laboratory Performance

The review of the results and any associated corrective actions of inter-laboratory comparison are discussed with relevant staff. Discussion of EQA results is done at departmental meetings. EQA results are also discussed and presented at the annual management review.

If EQA results do not meet predetermined criteria it is recorded as non-conformance in Q-Pulse and appropriate investigation into the failure is carried out. Corrective and preventative action is then implemented by departmental staff and reviewed by the clinical team in charge of the department concerned.

Results are reviewed to detect trends in performance that may indicate problems in the system. If performance trends in results that indicate problems are noted, a non-conformance is raised in Q-Pulse and appropriate investigation is carried out. Corrective and preventative action is then implemented and reviewed by the clinical team in charge of the department concerned.

A formal National Quality Assurance programme has been developed the by the Faculty of Pathology, RCPI for Anatomical Pathology. See EXT-CS-AP-12, National QA Programme in Histopathology SOP Monthly upload and local review of QA programme data.

5.6.4 Comparability of Examination Results

Where the same procedures, equipment and methods are in use, a comparison of results is performed. This is assessed through alternating analysis of EQA samples using the different procedures equipment and methods in place. The reports returned from EQA schemes in use in the laboratory include a comparability section in which results are compared to results from laboratories that use the same procedure, equipment, and method. The report score in comparison to other laboratories is checked as part of the EQA results review process. Any differences in comparability of results are discussed and users should be notified.

5.7 Post Examination Process

5.7.1 Review of Results

Only authorised personnel (trained personnel) shall review, evaluate and authorise the release of results. The review and release process is defined by procedure. This is described in procedure Review and Release of Results, MP-GEN-RESREL.

5.7.2 Storage, Retention and Disposal of Clinical Samples

The laboratory follows a procedure for the control of clinical material. It encompasses the procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. After testing, primary specimens and portions of specimens are stored in accordance with legal and clinical requirements as per the procedure for Control of Clinical Material, MP-GEN-CLINCON. Primary specimens, portions of specimens and material used in the testing process but no longer required, are disposed of safely in accordance with hospital procedures.

5.8 Reporting of Results

5.8.1 General

Laboratory management is responsible for approving the format of the test reports. The format review process is cognisant of the view and opinions of the hospital Consultants and other users of the laboratory services.

The reports (hard copy and electronic) are of a standard format which has been approved by laboratory management. Hardcopies of the printed report as required are issued on the day of test report release and reviewed for mistakes at authorisation stage, in accordance with departmental policy. Hardcopy printed reports are issued to the ward indicated on the request form for the patient's file. Hardcopy reports are issued as standard for requests received on paper request forms and reports received from referral laboratories.

Electronic reports are filed to the patients' chart, to the message centre of the clinician who requested the test and to the location pool where the patients chart resides.

All interim reports are followed by a final report. A supplementary report is issued to communicate additional information.

An amended report is issued where a major change to the diagnosis is made.

A corrected report is issued where there is a minor change (e.g. spelling or correction of a dimension).

Copies of reported results are retained electronically on the Winpath LIS. This ensures prompt retrieval of the information. The master copy of the hardcopy printed report is assigned to the patient file and is controlled by the medical records department.

The electronic and hardcopy records are maintained permanently (at least 30 years).

Reports are formulated to include information necessary for the interpretation of examination results where required. Results that are outside biological reference ranges are flagged. There is a comment code available in all departments to add comments to the test result if required.

Laboratory management and the requestor share responsibility for ensuring that the reports are available for review/interpretation by a responsible person in a timeframe that complies with agreed arrangements. The turnaround times for the release of results and blood products are stated in the Primary Specimen Collection Manual, PP-CS-LM-4. The turnaround times are monitored, recorded and reviewed. The review process feeds into the AMR process. Turnaround times are set to reflect clinical need. Where results are delayed, with a potential to compromise patient care, then such events will be documented as nonconformities. Corrective action in such cases includes communicating the reason for delay to the requesting clinician, medical Consultant and Clinical Governance as appropriate.

5.8.2 Report Attributes

The laboratory includes the following reports attributes to ensure results are communicated effectively:

a) Comments on sample quality that may affect results.
b) Comments regarding sample stability with respect to acceptance/rejection criteria.
c) Critical results.
d) Interpretative comments on reports where required.
e) The following text will be appended in the footer of all hardcopy printed reports for Haematology, Biochemistry and Microbiology, where accredited activities are being reported: *'An INAB accredited testing laboratory Reg No 240MT. Excludes tests performed in referral laboratories'.*
f) The following text will be appended in the footer of all hardcopy printed reports for Blood Transfusion, where accredited activities are being reported: *'An INAB accredited testing laboratory Reg. No 240MT. Excludes tests performed in referral laboratories. ®Denotes tests performed in a non INAB accredited referral laboratory'.*
g) The following note will be added to the body of each Histology hard copy printed report and electronic report: *'The NMH is an INAB accredited testing laboratory. Registration number 240MT. This covers testing carried out in this facility. For histology this excludes C9; Adipophilin; GATA 3; Alcian Blue; Grocotts; Alcian Blue/PAS; ZN; Reticulin; Elastin VG; MSB; Van Gieson; PAX8 and SARS CoV-2'.*
h) The following text will be visible on Blood Transfusion, Haematology, Biochemistry and Microbiology electronic reports for where accredited activities are being reported: *'The NMH is an INAB accredited testing laboratory (Reg.No. 240MT). Tests performed in referral laboratories are excluded from this scope'.*

5.8.3 Report Content

Reports include:

a) Clear identification of the test(s) and where appropriate the test procedure.
b) Identification of the laboratory that issued the report.
c) Identification of any tests that have been performed by a referral laboratory.
d) Patient's full name, date of birth, home address and destination of report on each page.
e) Name and contact details of the requesting Consultant/GP.
f) Date of primary specimen collection and time when relevant.
g) Primary specimen type (where appropriate).
h) Measurement procedure, where appropriate.
i) Results of the examination reported in SI units or units traceable to SI units as applicable. Refer to ISO Guide 31.
j) Biological reference intervals, clinical decision values, where applicable.
k) Interpretation of results where appropriate.

l) Free text or predefined laboratory comments to comment on the adequacy of primary specimen or other factors, which may have impacted on the trueness of the result and interpretations form referral laboratories are included.
m) Identification of tests undertaken as part of a research or development programme and for which no specific claims on measurement performance are available.
n) Identification of the person who authorised the release of the report. The date and time of authorisation is recorded on the report. However, all authorisation transactions including name are recorded electronically and are available for review on the LIS transaction log. Medical Council Registration number is included for all reports authorised by medical staff. Pre-authorised results (electronic signature COMP) are deemed authorised under the authority of Consultant in charge of the department. Results from referral laboratories, where printed on NMH paper are authorised by COMP. The name of the referral laboratory is indicated in the body of the report. The referral/back up laboratory report number is recorded internally on Winpath for reference.
o) Date of report and time of release. All time release transactions are recorded electronically and are available for review on the LIS transaction log.
p) Page number to total number of printed pages e.g. Page 1 of 2.

5.9 Release of Results

5.9.1 General

The release of results process is defined by procedure. This is described in Review and Release of Results, MP-GEN-RESREL. The following conditions are met:

a) When the quality of the primary sample received is unsuitable for testing or could compromise the result it is indicated in the report. Reasons for this include:
    - Incorrect volume of specimen.
    - Specimen clotted inappropriately.
    - Haemolysed/lipaemic specimens.
    - Specimens received that are too old for analysis.

Where the quality of samples does not conform to the requirements, the reason for non - acceptance is added to the report. If no examination is performed for a test, the reason for rejection is included as a comment in the body of the report. If the result may have been compromised due to quality of the sample, a test format code is added in accordance with the specimen reception procedure. These comments are included in the body section of all reports.

b) The laboratory has procedures in place, for immediate notification of clinical personnel when examination results for critical properties or parameters fall within documented critical intervals. Where the results of Anatomical Pathology investigation require immediate or unanticipated action by the clinician, the Histopathologist makes direct contact with the clinician. Where results achieve the defined alert/critical values, laboratory personnel communicate with relevant clinical personnel and the record of this communication in Winpath shows the following details:
    - Date and time of communication.
    - Identity of the laboratory staff member.
    - Identity of the person notified.
    - The examination results and any other comment relevant to the communication, including difficulties encountered.

They should also have the appropriate interpretative comment added in accordance with the protocol for the investigation.

c) In accordance with laboratory policy to ensure that all results are legible and without mistakes, all authorised and/or printed reports are reviewed prior to dispatch to ensure

demographic correctness and completeness of examination. To ensure that reports are received only by those persons authorized to receive them, hardcopies are delivered directly by the Pathology Department to ward receptions and clinics. All reports for 'outlying clinics' are delivered to obstetric outpatients for review and subsequent delivery. All reports for community midwives are delivered to their office. All external reports are posted directly to clinicians, excluding Blood Transfusion external reports that are distributed to the requesting GP via Health Mail account.

d) In general incomplete reports are not issued on investigations requested to allow for all results to be viewed together. However, when results are transmitted as an interim report they include the outstanding tests with a result of "To Follow" where appropriate. Exceptions may be made when analysis is protracted and delay in reporting is anticipated. Results of Full Blood Counts may be released prior to the completion of the manual differential examination process. Results of microscopic examinations of microbiological samples may be released prior to the final culture and sensitivity report. It is policy that all incomplete results made available to clinicians should be technically validated.
e) Where results are distributed by telephone there are processes for ensuring that results, reach only the intended recipient. All results distributed by telephone are followed up with a written report. Results that should be telephoned include those falling outside defined limits and they should be phoned as per the telephoning of reports procedure, LP-GEN-TELREP. In the general results are telephoned when:
    - There is a comment on the request form asking for results to be telephoned.
    - The results are abnormal or unexpected, as defined by procedure.
    - The result deviates significantly from previous results.
    - Urgent action by clinical staff is required.

The telephoning of reports should be documented in Winpath as outlined in LP-GEN-TELREP.

5.9.2 Automated Selection and Reporting of Results

Some reports for particular sample types auto-authorise in Microbiology and Haematology following completion of the results. This is defined by department in PP-CS-MIC-66 and PP-CS-HAE-29. All authorised and/or printed reports are reviewed prior to dispatch to ensure demographic correctness and completeness of examination. Hardcopies of reports are then delivered directly by the Pathology Department to ward receptions and clinics.

5.9.3 Revised Reports

In assuring quality of service to users it may be necessary to recall a result or to amend a report. The procedure in place in the laboratory outlines the criteria for issuing amended reports and the procedure to be followed when recalling results and or issuing amended reports. Departmental procedures are operable throughout the Department of Pathology and Laboratory Medicine, and ensures that:

a) The new amended report clearly outlines that it is a deviation from the original, and the original copy is left in the patient's chart and is marked as incorrect.
b) Where a report has been amended the clinical area will be notified directly and made aware of the amendment.
c) The revised report shows the time and date of the change and the name of the person responsible for amendment.
d) The original report and the correct report are retained on Winpath, the original copy is also left in the patient's chart and is marked as incorrect.

5.10 Laboratory Information Management

5.10.1 General

The laboratory has access to the data and information required to provide a service which meets user needs through a number of systems. These include:

- The laboratory information system (LIS), Winpath.
- A patient manager system, iPIMS.
- An electronic health record, MN-CMS.
- A laboratory quality management system, Q-Pulse.

Laboratory information systems have a major impact on all phases of operating activity process, and procedures. The Winpath LIS captures, processes, reports and stores data concerning the identification of patients and specimen analysis. The system is online in all the wards via Winpath Ward Enquiry 5. This facilitates result enquiry for users of the Pathology service. Authorised results transfer to MN-CMS and can be reviewed in the patient electronic health record available in every clinical area.

Laboratory management ensures confidentiality of the patient is maintained at all times by adhering to the confidentiality policy. This applies to all employees and is detailed in all contracts of employment. Acceptance of the terms and conditions of the contract indicate compliance and acceptance of this policy.

5.10.2 Authorities and Responsibilities

The Laboratory Manager and Information Systems Scientist are responsible for the local management of the LIS, and ensure that all LIS related procedures in place are strictly adhered to. The infrastructure, servers and hardware are the responsibility of the ICT department.

The laboratory defines the authorities and responsibilities of all personnel who use the system through a password control system. Access to Winpath is password controlled. Passwords are designated by the laboratory manager and different levels of access are assigned to staff depending on the requirements of their position. Access levels define who has authority to:

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

An audit trail displays any actions that were made on a particular laboratory number including the identification of the person who performed it.

5.10.3 Information System Management

Laboratory management and the IT department are responsible for ensuring that the information systems in use in the laboratory for the collection, processing, recording, reporting, storage, retrieval of examination data and that information is:

a) Suitably validated as adequate for use in the facility by the supplier before introduction. Any changes to the system must be authorised and documented before implementation. This is achieved through the change management procedure in Q-Pulse. The validation and verification should include functioning of interfaces between the LIS and laboratory instrumentation or the patient information system.

b) The system, including day to day running is documented. This is documented in LP-GEN-WINPATH, and is available to all users.
c) Computer programmes and routines are adequately protected via passwords and permissions to prevent access, alteration or destruction by casual or unauthorised persons.
d) Safe guarded against tampering or loss. The IT Department is responsible for maintaining the system backups. This is done nightly Monday to Saturday i.e. 6 times a week.
e) Computers and automated equipment are operated in an environment which complies with supplier specification. In the event of non-computerised systems being used conditions should safeguard the accuracy of manual recording and transcription.
f) CliniSys has an annual preventative maintenance contract in place which covers the maintenance of the integrity of the operating system and laboratory application software. All system failures are recorded in Q-Pulse and appropriate corrective and preventative actions put in place as per policy.
g) The systems are managed in compliance with national and international requirements regarding data protection this is documented in the hospital management of data and information document.

Procedures are established and implemented for protecting the integrity of data at all times. This ensures that test results, associated information and comments are accurately reproduced. Winpath has a report preview function that allows the user to view the finished report electronically before printing.

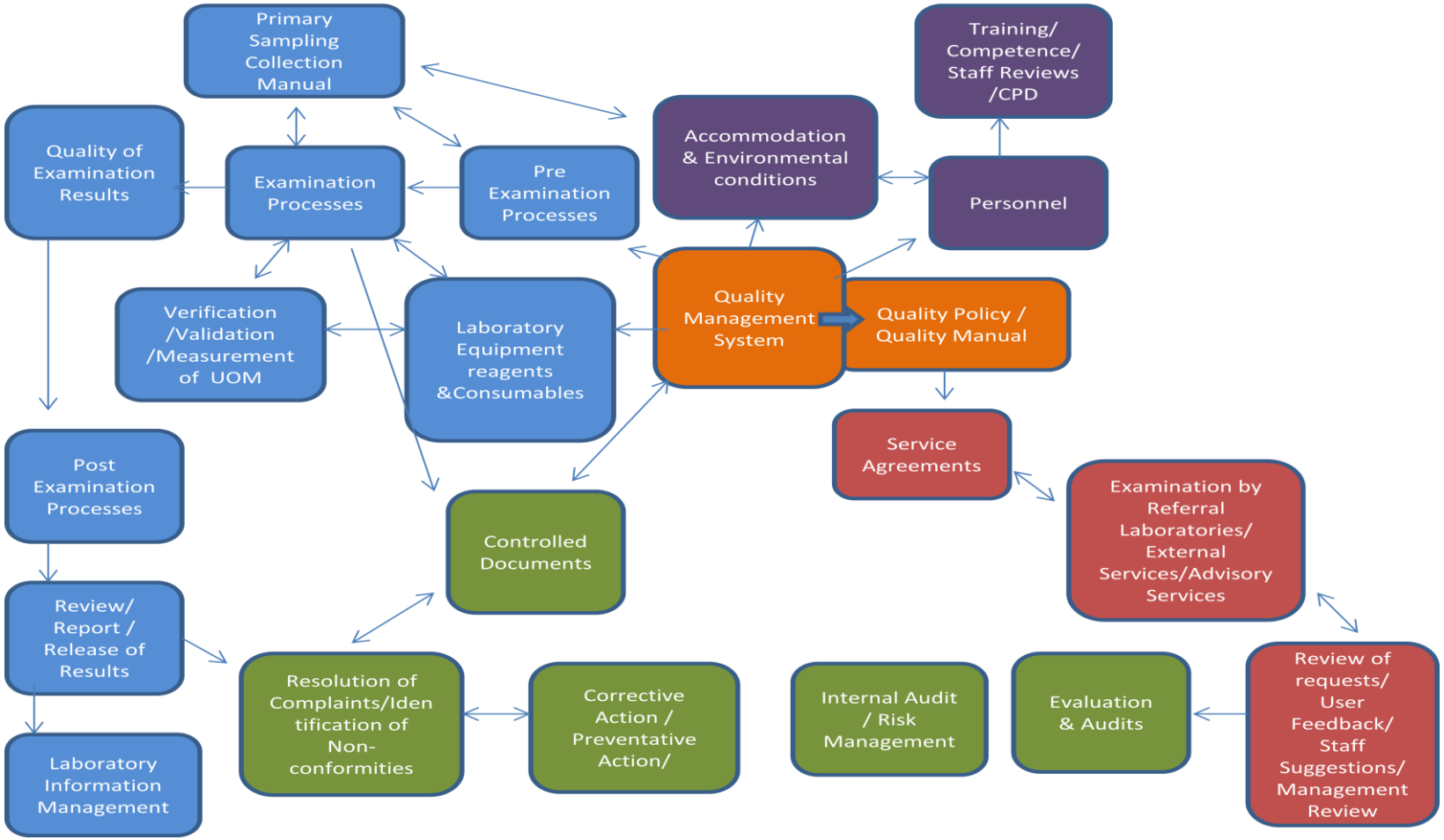
The laboratory verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hardcopy, where relevant through the procedures, PP-CS-LM-31, Management of Winpath, and PP-CS-LM-32, Advanced Use of Winpath; and through the annual audit, IT Dept Verification of Electronically Stored Data.

5.10.4 System Failure

In the event of system failure during normal working hours, the Laboratory Manager is first contacted, and if necessary either Information Systems Scientist, the IT Department or a service engineer from CliniSys is called. Instructions for system failure are available on Q-Pulse.

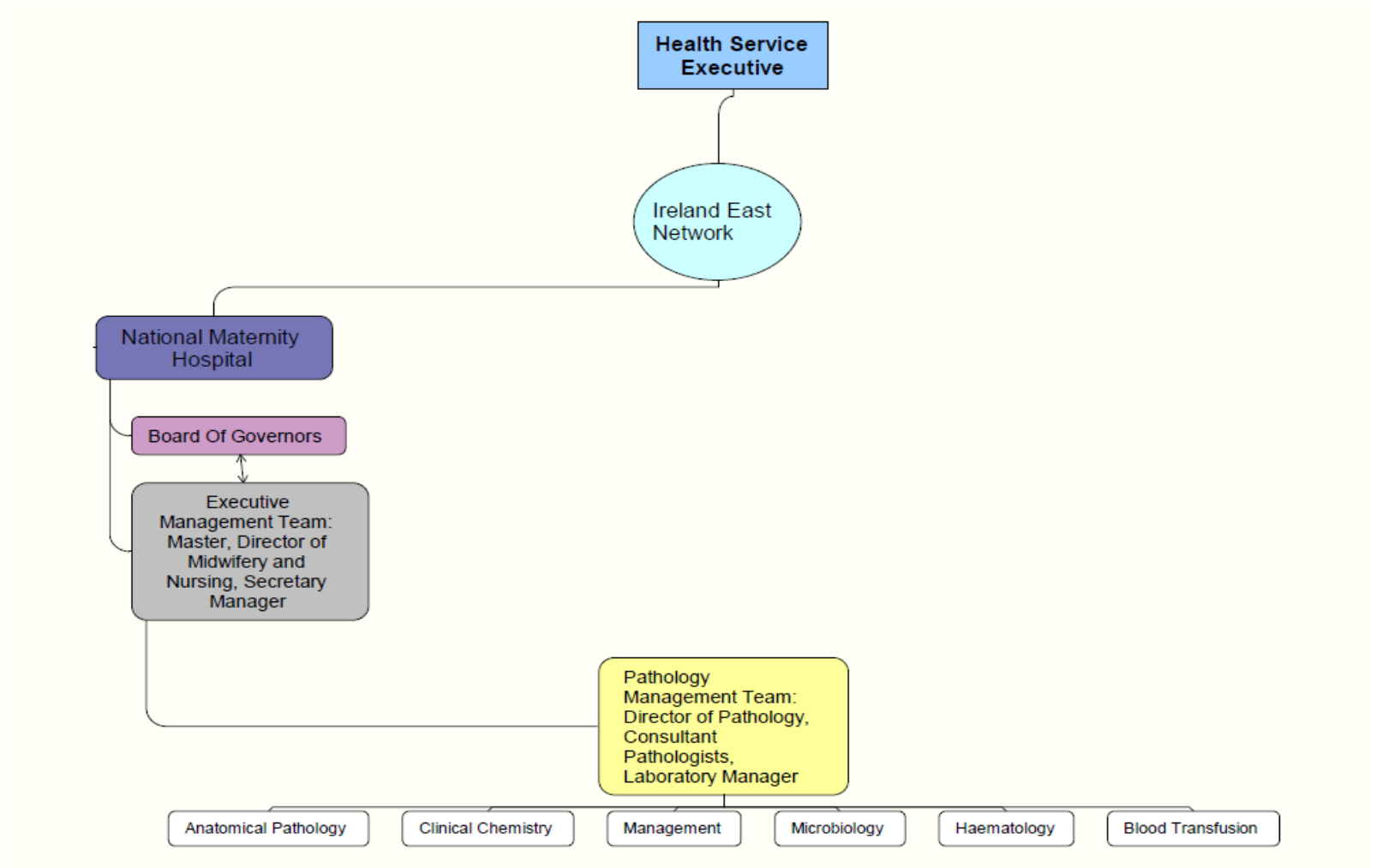
6 Appendices

6.1 Pathology Department Quality Assurance Process Flow



6.2 Department of Pathology and Laboratory Medicine Organisational Charts

6.2.1 National Maternity Hospital



6.2.2 National Maternity Hospital Department of Pathology and Laboratory Medicine

Convention for organisational chart:

1. Black lines indicate Direct reporting relationships and flow up the chart
2. Red Lines indicate Direct and Clinical reporting relationships and flow in the direction of the arrow
3. Green Lines indicate liaison relationships and flow in the direction of the arrow