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| **QUALITY MANUAL** | |
| This Document together with any documents which it references, details the Quality Management System of the Department of Haematology, North Glasgow Division, NHS Greater Glasgow & Clyde. All policies and procedures described within are mandatory in the Department of Haematology, North Glasgow Sector. | |
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# Abbreviations and Acronyms

|  |  |
| --- | --- |
| ACH | Ambulatory Care Hospital |
| AGM | Assistant General Manager |
| AMR | Annual Management Review |
| BSQR | Blood Safety and Quality Regulations |
| CCS | Consultant Clinical Scientist |
| CPD | Continuing Professional Development |
| EQA | External Quality Assessment |
| GGH | Gartnavel General Hospital |
| GRI | Glasgow Royal Infirmary |
| HCPC | Health and Care Professions Council |
| HSE | Health and Safety Executive |
| IBMS | Institute of Biomedical Science |
| IQC | Internal Quality Control |
| ISO | International Organization for Standardisation |
| JD | Job Description |
| LIMS | Laboratory Information System |
| MHRA | Medicines and Healthcare Products Regulatory Authority |
| MSC | Managed Service Contract |
| NHS | National Health Service |
| NHSGGC | NHS Greater Glasgow and Clyde |
| QM | Quality Manual |
| QMS | Quality Management System |
| RCA | Root Cause Analysis |
| RF | Radio Frequency |
| SLA | Service Level Agreement |
| SLM | Sector Laboratory Manager |
| SNBTS | Scottish National Blood Transfusion Service |
| SOP(s) | Standard Operating Procedure(s) |
| STB | Stobhill ACH |
| TP | Transfusion Practitioner |
| TSM | Technical Services Manager |
| UKAS | United Kingdom Accreditation Service |
| UoM | Uncertainty of Measurement |
| WACH | West Glasgow ACH |

# Introduction

This Quality Manual describes the Quality Management System of the North Glasgow Sector Haematology Department. This Quality Manual can be regarded as the index volume to separate documentation of management, laboratory, clinical and quality procedures.

The sections of the Quality Manual are arranged so that they follow in sequence the ISO: 15189-2012 Standards [ECD-ALL-GDL-027]. After the title of each section or sub section the relevant standard of the ISO15189-2012 standards is referenced in brackets (x.x.x.). Reference to other standards may be included where relevant. In each section there is a brief description of the way in which the Department seeks to comply with the particular standard and references are given to appropriate documents using their QMS reference number [ABC-ABC-ABC-XXX]. The full title of the document can be found in the appendices, see Appendix 1. Publications relative to Accreditation and Regulatory bodies can also be found in the appendices, see Appendix 2. All referenced documents can be found on the department’s QMS system; Q-Pulse.

## Overview of the organization

As part of the diagnostic services of NHSGGC, the Department of Haematology North Glasgow Sector provides Haematology, Haemostasis, Blood transfusion and Diagnostic Haemato-oncology services from four sites (Glasgow Royal Infirmary, Gartnavel General Hospital, Stobhill ACH and West Glasgow ACH) to service users for the benefit of the patient and population. Additionally the department provides blood for transfusion to the Lightburn Hospital (NHSGGC) and the Marie Curie Hospice (Glasgow). Details of the services provided on each site can be found in the Departmental User Handbook [MAI-ALL-ALL-009]. With the exception of the Diagnostic Haemato-Oncology service all locations are staffed from a pool of staff based at the Glasgow Royal Infirmary.

The laboratory has adopted a quality management system for the purpose of the effective and efficient use of its resources. All employees are committed to the culture of quality. All staff share responsibility for identifying nonconformities or opportunities for improvement and recording these instances so that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers. All aspects of the quality management system; including (but not exclusive to) organisation, reporting structures, internal audit, incident reporting, training and competency are applied equally across all the laboratory sites and processes within the North Glasgow Sector in accordance with the relevant regulatory and accreditation standards [ECD-ALL-GDL-027, ECD-ALL-GDL-028, ECD-ALL-GDL-042, ECD-ALL-GDL-065, ECD-ALL-MAN-002] and any subsidiary documentation see appendix 2.

## NHSGGC Mission statement

“Deliver effective and high quality health services, to act to improve the health of our population and to do everything we can to address the wider social detriments of health which cause health inequalities”.

## Objectives

The objectives of the laboratory are to produce accurate, reliable and timely analyses' results. To maintain an effective quality management system. To ensure compliance with all relevant statutory requirements. To comply with all health and safety requirements.

The department senior management through the Quality Manager contribute to the implementation of the quality management system to achieve the defined objectives.

## Scope

This Quality Manual describes the quality management system (QMS) of the Department of Haematology, North Glasgow Sector**.**

Its scope is:

* **Internal use:** To communicate to staff the laboratory’s quality policy and quality objectives. To make the staff familiar with the processes used to achieve compliance with quality requirements. This facilitates the implementation of the quality management system as well as ensuring its maintenance and required updates during altering circumstances. This allows effective communication and the control of quality related activities and a documented base for quality system audits.
* **External use:** To inform the service users about its quality policy as well as its implemented quality management system and of compliance with quality.

# Quality Policy Statement

Senior management is dedicated to providing the resources necessary to maintain the laboratory quality management system.

The laboratory is committed to continual improvement, meeting internal and service user requirements and providing a basis for the establishment and review of the quality objectives.

Quality practices are communicated within the organisation and are understood and adhered to by all employees. The laboratory ensures a competent workforce to deliver quality results in a timely manner according to the Blood Safety and Quality Regulations 2005 (amended 2007) [ECD-ALL-GDL-028] and The Medicines for Human Use (Clinical Trials) Regulations 2004 (amended 2005 and 2006) [ECD-ALL-GDL-065] as regulated by the MHRA. Also ISO15189-2012 [ECD-ALL-GDL-027] as assessed by UKAS. The laboratory ensures that each section partakes in and documents internal quality assurance activity. The laboratory ensures that each department belongs to and participates in, appropriate External Quality Assurance schemes with evidence of performance review. The laboratory ensures that each department is routinely active in addressing Health & Safety, Staff training and development, appropriate equipment maintenance and internal audit.

# Organisation and Management Responsibility (4.1)

## Organisation (4.1.1. and 4.1.1.1.)

The laboratory ensures to deliver quality results in a timely manner according to the Blood Safety and Quality Regulations 2005 (amended 2007) [ECD-ALL-GDL-028], The Medicines for Human Use (Clinical Trials) Regulations 2004 (amended 2005 and 2006) [ECD-ALL-GDL-065] and ISO15189-2012 [ECD-ALL-GDL-027].

### Legal Entity (4.1.1.2.)

The laboratories of the Department of Clinical and Laboratory Haematology, North Glasgow Sector, NHSGGC, are a constituent of the Diagnostics Division in the Acute Services of NHS Greater Glasgow and Clyde. The department provides routine and specialised haematology services from 4 sites situated at; Glasgow Royal Infirmary, Gartnavel General Hospital, Stobhill ACH and a hot lab at West Glasgow ACH that operates during Haematology clinic hours only (as required). It provides Blood Transfusion services from one site, Glasgow Royal Infirmary. Details of the services provided on each site can be found in the Departmental User Handbook [MAI-ALL-ALL-009].

### Ethical Conduct (4.1.1.3.)

The Department of Haematology is not engaged in any activity that might influence its technical or clinical judgment. The laboratory is not committed to any commercial, financial or other pressure provided by any particular organisation that could influence its technical or clinical judgment or affect its competencies and trust.

Laboratory management ensures the following:

* That there are no activities that could compromise laboratory performance.
* That there are appropriate procedures to ensure ethical respect of patient samples and confidentiality of patient information. [MAP-ALL-ALL-002, MAP-ALL-ALL-018, ECD-ALL-POL-006, ECD-ALL-POL-011, ECD-ALL-POL-013]
  + The duties and responsibilities of laboratory personnel are defined.
  + That appropriate communication is established within the laboratory.
  + That a quality manager and a health and safety officer aredesignated.
  + That quality, continual improvement and user satisfaction are the personal responsibility of all departmental staff.

### Laboratory Director (4.1.1.4.)

Each site from which the service operates from has a team of clinicians. These report to the head of service. Each clinician may have additional duties as out lined in their job description/job plan.

The following table details the responsibilities as detailed in Section 4.1.1.4 of the ISO15189 standard and to whom those duties may be delegated.

|  |  |  |
| --- | --- | --- |
| Duty | Responsibility | Comment |
| Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities. | Lead clinician, TSM, SLM, CCS and laboratory management team. | Through HMT and MSC budget meetings [ECD-ALL-POL-040] |
| Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required. | Lead clinician, TSM, SLM, CCS, Quality Manager and TP | Senior laboratory staff deal directly with UKAS and MHRA. User surveys and SLA’s with outside service users. |
| Duty | Responsibility | Comment |
| Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users | Medical staff – Regional management team.  Lab staff – Diagnostic management team. | Training and education records kept for all staff, people module of QMS. [MAP-ALL-ALL-026] |
| Ensure the implementation of the quality policy. | Lead clinician, TSM, SLM, CCS and Quality Manager | Controlled document in QMS. [MAP-ALL-ALL-014] |
| Implement a safe laboratory environment in compliance with good practice and applicable requirements. | TSM, SLM, CCS and Health and Safety Officer. | H&S committee, relevant items raised at staff meetings. |
| Serve as a contributing member of the medical staff for these facilities served, if applicable and appropriate. | Lead Clinician | Detailed in this document |
| Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results. | All Consultant medical and registrar staff. | Medical staff are available 24 hours a day. |
| Select and monitor laboratory suppliers | Diagnostic management team. | Controlled through managed service contract. |
| Select referral laboratories and monitor the quality of their service. | TSM, SLM, CCS, Technical Leads and Quality Manager | All referral labs are checked continuation of accreditation using form. [QAC-ALL-ALL-048] |
| Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations. | TSM, SLM, CCS and Quality/Training Manager | All staff complete mandatory training, NEQAS, CPD, and attend scientific meetings [MAP-ALL-ALL-026] |
| Define, implement and monitor standards of performance and quality improvement of the medical laboratory service and services. | Lead clinician, TSM, SLM, CCS, Technical leads, Quality Manager, Transfusion practioner | Defined through quality manual and monitored via balanced scorecard monthly at HMT. [QM-ALL-ALL-001] |
| Monitor all work performed in the laboratory to determine that clinically relevant information is being generated. | Lead clinician, TSM, SLM, CCS, Technical Leads and Quality Manager. | Audit and non conformance modules in QMS, Incident, quality and HTT meetings. |
| Address any complaint, request or suggestion from staff and/or users of laboratory services. | Lead clinician, TSM, SLM, CCS, Quality manager and Technical Leads | Audit and non conformance modules in QMS, Incident, quality, staff, HMT and HTT meetings. |
| Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable. | Lead clinician, TSM, SLM, CCS and Technical Leads | [LAP-ALL-ALL-033] |
| Plan and direct research and development, where appropriate. | Lead clinician, TSM, SLM, CCS and Technical Leads. |  |

### Organisational charts

The laboratory collaborates with other departments including the human resources department, Education and Learning department, finance department, procurement department, Facilities as well as other support services.

The laboratory and the Diagnostics Division organisational structures are shown in the charts below. Solid lines are those of accountability. Dashed lines show reporting responsibilities. The different colours show reporting/accountability levels.

#### Diagnostics Division

#### Department of Haematology

## Management responsibility (4.1.2.)

### Management Commitment (4.1.2.1.)

The management commitments as detailed in the ISO15189 standard [ECD-ALL-GDL-027] are listed below with any relevant documentation in which the detailed description of the means of complying with the standard can be found.

* Communicating to laboratory personnel the importance of meeting the needs and requirements of users [SCM-MIN-GSM-001 onwards]
* Communicating the regulatory and accreditation requirements [SCM-MIN-GSM-001 onwards, SCM-MIN-QM-001 onwards and SCM-MIN-ISO-001 onwards]
* Establishing the quality policy [MAP-ALL-ALL-014]
* Ensuring that quality objectives and planning are established [MAI-ALL-ALL-073]
* Defining responsibilities, authorities and interrelationships of all personnel [QM-ALL-ALL-001]
* Establishing communication processes
* Appointing a quality manager
* Conducting management reviews [MAP-ALL-ALL-013]
* Ensuring that all personnel are competent to perform their assigned activities [MAP-ALL-ALL-026]
* Ensuring availability of adequate resources to enable the proper conduct of pre-examination activities.
* Examination and post-examination activities [MAP-ALL-ALL-010, MAP-ALL-ALL-011, MAP-ALL-ALL-020 and LAP-ALL-ALL-007]

### **Needs of Users** (4.1.2.2)

The needs of the users of the department are translated into requirements, which form the focus of objective setting and planning. The needs of the users are kept under constant review, achieved through periodic meetings, informal discussion and communication, and from user feedback [SCM-MIN-GSM-001 onwards and SCM-MIN-QM-001 onwards].

Assessment of user satisfaction and complaints is conducted on a regular basis and consideration of the findings form part of the annual management review.

### Quality Policy (4.1.2.3.)

The Quality policy [MAP-ALL-ALL-014] of the Haematology department is in appendix 3 of this quality manual.

### Quality Objectives and Planning (4.1.2.4.)

The quality objectives [MAI-ALL-ALL-073] for the Directorate are discussed, agreed and documented at the Annual Management Review meeting between the senior management team in Haematology and the Clinical Lead and senior Diagnostics Directorate staff. The Laboratory Management Team defines the quality objectives of the laboratory and is responsible for ensuring that plans are made to meet these objectives.

### Responsibility, Authority and Interrelationships (4.1.2.5.)

**Clinical Head of Service (CHS):** Dr Edward Fitzsimons deputised by Sector Lead Clinicians as appropriate.

**General Manager (GM):** Robert Gardiner

**Assistant General Manager (AGM):** Jane Gibb, reports to General Manager deputises for General Manager.

**Lead Clinician North Sector:** Dr. Louisa McIlwaine, deputised by Dr Edward Fitzsimons (all sites) reports to clinical head of service.

**Technical Services Manager (TSM):** Margaret Jane Cartwright (all sites), deputises for AGM as appropriate, reports to assistant general manager.

**Sector Laboratory Manager (SLM):** Arlene David (all sites except Diagnostic Haemato-Oncology), deputises for TSM, reports to TSM

**Quality and Training Manager (QM):** Kevin Marriott, reports to TSM (all sites) deputised by Arlene David (Quality) and Lynsey Whitefield (Training).

**Consultant Clinical Scientist:** Dr Darren O’Brien reports to AGM (Diagnostic Haemato-Oncology only).

**Haemostasis Technical Manager:** Caroline Lawrence, (all sites except WACH) reports to TSM deputises for SLM.

**Haemato-Oncology Technical Manager:** Allyson Doig, reports to TSM and Consultant Clinical Scientist (Diagnostic Haemato-Oncology only) deputises for Consultant Clinical Scientist.

**Health and Safety Officer:** Grainne Hickman reports to TSM deputised by Sean Glackin.

|  |  |
| --- | --- |
| Sector Lead Clinician | The Sector Lead Clinician has overall clinical responsibility for the Department, and specific responsibility for medical staff recruitment. |
| Consultant Medical Staff | Consultant Medical Staff have responsibilities for Clinical and Laboratory Haematology services and as defined in Job Plans, are accountable to the Sector Lead Clinician. |
| Technical Services Manager | The Technical Services Manager has specific accountability for laboratory operations of the Department. In addition, in conjunction with the General and Assistant General Manager, the Technical Services Manager has accountability for financial operations of the Department.  In the absence of the Technical Services Manager, the Sector Laboratory Manager shall assume responsibilities. [MAI-ALL-ALL-119] |
| Sector Laboratory Manager | Responsibilities of the Sector Laboratory Manager are defined in [MAI-ALL-ALL-095] |
| Quality, Training and POCT Manager | Responsibilities of the Quality, Training and POCT manager are defined in [MAI-ALL-ALL-096] |
| Consultant Clinical Scientist | Responsibilities of the Consultant Clinical Scientist are defined in [MAI-ALL-ALL-124] |
| Haemostasis Manager | Responsibilities of the Haemostasis manager are defined in [MAI-ALL-ALL-094] |
| Haemato-Oncology Manager | Responsibilities of the Haemato-Oncology manager are defined in [MAI-ALL-ALL-093] |

See also section 3.1.4.1 and 3.1.4.2

There are four senior BMS staff in Routine Haematology. Although all are principally based on the GRI site each of these staff has responsibility for one site. The senior BMS responsible for each satellite site is the daily (primary) point of contact for their site and is responsible for monitoring all matters relating to quality control, quality assurance, equipment, stock and performance of the service. They are required to attend their site at least weekly (GGH) or monthly (STB, WACH).

### Site Responsibility

Outside of the Glasgow Royal Infirmary laboratory the following staff have day to day responsibility for the service at the other laboratories.

Gartnavel General Hospital: Gillian Kemp

Stobhill ACH: Linsay Thomson

West Glasgow ACH: Linsay Thomson

With the exception of the Diagnostic Haemato-Oncology service all sites are staffed from a pool of appropriately trained BMS staff based at Glasgow Royal Infirmary and report via the structure in .

### Communication (4.2.1.6.)

The management ensures appropriate communication takes place to keep all staff members informed. Meetings are held covering various aspects of the function of the laboratory. Minutes are taken of these meetings and where stated are made available on Q-Pulse for all staff.

#### Departmental Meetings

##### General Staff Meeting

General Staff Meetings are held monthly for all personnel in the department. These meetings cover all locations within the North Glasgow sector.

During the meetings:

* Information on general organisation, actions and projects is communicated.
* Information on departmental organisation, actions and projects is communicated.

Minutes and Action Points are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-GSM-001 onwards].

##### Quality Meeting

Quality Meetings are held monthly and all personnel may attend. These meetings cover all locations within the North Glasgow sector [QMS-ALL-ALL-030].

During the meetings:

* Information on the QMS is communicated.
* Information on CAPA, Internal Audit, External Audit, validation/verification, EQA, IQC, Quality Objectives, BSQR, ISO15189 actions and projects is discussed and communicated.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-QM-001 onwards].

##### Incident Meeting

Incident Meetings are held fortnightly and all personnel may attend. These meetings cover all locations within the North Glasgow sector [QMS-ALL-ALL-030].

During the meetings:

* Information on the clinical incidents reported on DATIX is communicated.
* Information on Corrective Action and Preventative Action is discussed and communicated.

Minutes and Action Points are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-INC-001 onwards].

##### Haemato-Oncology Staff Meeting

Haemato-Oncology Staff Meetings are held monthly for all Haemato-Oncology personnel. These meetings are provided to the Haemato-Oncology staff who are permanently based at the Gartnavel Hospital site and who are logistically unable to attend the General staff meeting.

During the meetings:

* Information on general organisation, actions and projects is communicated.
* Information on departmental organisation, actions and projects is communicated.
* Information on the service provided to the West of Scotland Regional stem cell Transplant programme.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-GGH-001 onwards].

##### Haemostasis Team Meetings

Haemostasis Team Meetings are held quarterly for all Haemostasis personnel in the department.

During the meetings:

* Information on Haemostasis, actions and projects is discussed and communicated.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-HTM-001 onwards].

##### Senior Staff Meetings

Senior Staff Meetings are held bi-monthly for all senior personnel from all locations in the department.

During the meetings:

* Information on general organisation, actions and projects is communicated.
* Information on departmental organisation, actions and projects is communicated.
* Information on CAPA, Audit, validation/verification, EQA, IQC, Quality Objectives, BSQR, ISO15189 actions and projects is discussed and communicated.
* Information on Haematology management; organisation, actions and projects is discussed and communicated.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-SSM-001 onwards].

##### Hospital Transfusion Team Meetings

Hospital Transfusion Team Meetings are held 6 weekly for senior Transfusion personnel in the laboratory.

During the meetings:

* Information on Blood Transfusion, actions and projects is discussed and communicated.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-HTT-001 onwards].

#### Non Departmental Meetings

As well as departmental meetings staff also attend and participate in other meetings associated with the Diagnostics Division. Some of the meetings make their minutes available.

##### Haematology Management Team Meeting

Haematology Management Team Meeting: This occurs monthly and is for senior management level staff within Laboratory Medicine.

* Information from all Sectors is communicated.
* Financial performance is discussed.
* Compliance with KPIs is communicated through Balanced Scorecard.
* Risk register is discussed and updated.
* Strategic decisions are made.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-HMT-001 onwards].

##### Quality Management and Compliance Meeting

Quality Management and Compliance Meetings are held bi-monthly and all Quality Management personnel may attend.

During the meetings:

* Information on the QMS is communicated.
* Information on CAPA, Audit, validation/verification, EQA, IQC, Quality Objectives, BSQR, ISO15189 actions and projects is discussed and communicated.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-QMC-001 onwards].

##### Overarching Transfusion Committee

Overarching Transfusion Committee: This occurs quarterly and is for senior blood transfusion management level staff.

Senior Staff Meetings are held bi-monthly for all senior personnel in the laboratory.

During the meetings:

* Information on general organisation, actions and projects is communicated.
* Information on strategic organisation, actions and projects is communicated.
* Information on strategic Haematology management; organisation, actions and projects is discussed and communicated.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SCM-MIN-OTC-001 onwards].

##### NHSGGC Point of Care Committee

NHSGGC Point of Care Committee The POCT Committee meets bi-annually for staff involved in the management of POCT.

During the meetings:

* Information on the administration and the safe and effective use of “Near Patient Testing” is discussed and communicated.
* Current guidelines and legislation is discussed and communicated.
* Information on strategic organisation, actions and projects is communicated.

Minutes are taken of the meeting these are distributed to the committee members.

##### Clinical Governance Meetings

Clinical Governance Meetings are held bi-monthly and selected personnel with responsibilities for quality, risk and incident management attend.

During the meetings:

* Information on clinical incidents is communicated.
* Information on CAPA, Audit, validation/verification, EQA, IQC, Quality Objectives, BSQR, ISO15189 actions and projects at a divisional level is discussed and communicated.

Minutes are taken of the meeting these are distributed to the attendees

##### MSC – Haematology Subgroup

These Meetings are held bi-monthly and are attended by the AGM, all Haematology TSMs, Specialty Section Managers, MSC Supplier Account Manager and representatives from third party suppliers.

During the meetings

* A review of performance within each section with each supplier is communicated.
* Areas of concern and non performance with suppliers are raised
* Single points of failure are indentified, risk assessed and appropriate remedial action identified.
* Actions are raised with MSC and third party suppliers.
* Further meetings to discuss areas of non compliance with suppliers can be arranged. These can be performance or financial issues.

Action points are taken at the meeting these are distributed to the attendees.

##### Haematology Finance Meeting

These Meetings are held bi-monthly and are attended by the AGM, all Haematology TSMs and Senior Management Accountant.

During the meetings

* Financial reports are scrutinised.
* Decisions are made on budget allocation.

Action points are taken at the meeting these are distributed to the attendees.

## Quality Manager (4.1.2.7)

The Quality Manager has the delegated responsibility and authority to:

* Ensure that processes needed for the Quality Management System are established, implemented, and maintained.
* Report 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.
* Ensure the promotion of awareness of users needs and requirements throughout the laboratory.

# Quality Management System (4.2)

## Documentation (4.2.2.1)

The core documentation of the quality management system consists of the following:

* Quality manual [QM-ALL-ALL-001]
* Quality policy [MAP-ALL-ALL-014]
* Quality objectives [MAI-ALL-ALL-073]
* Departmental Service Users Guide [MAI-ALL-ALL-009]

Policies, procedures and all other required documentation is controlled and can be found within the laboratories QMS system; Q-Pulse.

## Quality Manual (4.2.2.2.)

This document [QM-ALL-ALL-001] contains:

* The quality Policy [MAP-ALL-ALL-014] see appendix 3
* The scope of the quality management system
* The organisational structure. See sections 3.1.4.1 and 3.1.4.2
* The roles and responsibilities of laboratory management. See section 3.2.5
* The structure and relationships of documents within the QMS
* The managerial and technical activities that support the QMS

All staff have access to the Quality Manual. It is stored within the QMS system and new revisions are distributed to all staff upon release.

# Document Control (4.3)

The policy on document control is contained within the document [MAP-ALL-ALL-003].

Standard document templates [LAP-ALL-ALL-001, MAP-ALL-ALL-001 and ECD-ALL-POL-023] ensure that each document contains:

* A title
* A unique identifier
* The active date of the current edition
* A revision number
* The page number to the number of pages
* The authority for Issue

QMS documentation is subject to strict control and is subject to review and amendment when appropriate [MAP-ALL-ALL-003]. This control ensures for all locations that:

* All QMS documentation is approved for use by authorised personnel prior to issue.
* All QMS documents are uniquely identified
* There is traceability of date of issue,
* The revision version
* A version history
* The staff responsible for the authorisation for issue.
* There is a Master List that identifies all current authorised versions.
* All QMS documents are legible, readily identifiable and retrievable.
* All QMS documents are regularly reviewed and updated as required,
* Only current document versions are available to staff.
* All QMS access and user permissions are strictly controlled.

# Service Agreements (4.4)

## Establishment of Service Agreements (4.4.1, 4.4.2.)

The requirement to define the service users requirements, including where appropriate formal contracts is identified by the Department as an essential prerequisite of a quality service.

SLAs are considered as part of the negotiation of a service contract agreed between the Department and the user(s) andthe point where the level of service is formally defined. [MAP-ALL-ALL-024]

The Department acknowledges that:

* Each request accepted by the laboratory for an examination procedure is considered an agreement.
* Agreements to provide medical laboratory services take into account the request, the examination and the report.
* The agreement specifies the information needed on the request to ensure appropriate examination(s) and result interpretation(s).

# Referral Laboratories (4.5)

## Selection and Evaluation (4.5.1.)

The Departmental Referral Policy [MAP-ALL-ALL-017] contains the requirements for sample referral including handling, packaging and dispatch.

It also contains the procedures for recording the despatch of laboratory specimens to referral laboratories for testing and the subsequent management of results and reports received from referral laboratories.

The policy covers:

* The evaluation and selection of referral laboratories to perform referred examinations.
* The recording of analyses referred.
* A list of testing laboratories that samples are referred to also available in the user handbook [MAI-ALL-ALL-009].
* Recording of referrals include dates of dispatch and details of the referral laboratory.
* The monitoring of results and reports issued by referral laboratories.
* The respective responsibilities for the interpretation and reporting of referred examinations
* The arrangements with referral Laboratories are formally reviewed to ensure that requirements, including EQA performance and turnaround times are satisfactory to the requirements of the department and service users.

## Results from Referral Laboratories (4.5.1.)

The Departmental Referral Policy [MAP-ALL-ALL-017] contains the requirements for referral sample result reporting including.

* The identification of the referral laboratory or Consultant.
* The transcription and reporting of results and interpretative comments.
* The addition of any further comments as required.

# External Services and Supplies (4.6)

The Department operates a procedure for the selection and purchasing of equipment, reagents, calibration and quality control material and consumables.

NHSGGC operates a system of strict budgetary control. In accordance with Standing Financial Instructions [ECD-ALL-POL-040] the purchasing of supplies by the Department is controlled via use of an online purchasing system (PECOS).

In addition to this a system for Internal Supplies Ordering, used for general and office supplies from the Hospital Stores and Pharmacy Departments is also in use. The policies and procedures for use of this system are outlined within the Standing Financial Instructions [ECD-ALL-POL-040].

The majority of laboratory supplies including equipment, reagents, calibration and quality control material and consumables are purchased through the Managed Service Contract by the MSC supplier.

The Department:

* Selects and approves suppliers based on their ability to supply services, equipment, reagents and consumables in accordance with contracted requirements (non MSC).
* Is compliant with NHSGGC Policy and operates strict purchasing control procedures.
* Purchases goods, services, equipment and materials only from a list of selected and approved suppliers (non MSC).
* Monitors the performance of suppliers to ensure that purchased services or items consistently meet accepted criteria (non MSC).

# Advisory Services (4.7)

The Department provides a comprehensive routine and specialised Haematology, Haemostasis, Blood Transfusion and Diagnostic Haemato-Oncology service to service users both within and out with NHSGGC. The Departmental Clinical Team provides a clinical advisory service for service users within all the hospital sites and service users in General Practice. Patients may be referred directly to the clinical team or the team may suggest consultation or referral following the review of analytical results. The team works in close collaboration with other clinical colleagues where relevant to ensure effective clinical and laboratory input into patient investigation and management.

Specific contact and service details are detailed in the Service User Handbook [MAI-ALL-ALL-009] available on the NHSGGC website, StaffNet or in an electronic copy on request from the Quality Manager. This includes:

* The use of the service.
* Relevant sample types.
* The Turnaround Times of examinations.
* Any relevant request requirements.
* Available examinations.
* Uncertainty of Measurement for quantitative examinations.
* Any relevant factors that may affect examinations.
* The availability of Clinical Advise
* The availability of Technical advice

# Complaints (4.8)

The departmental Policy for Complaints [MAP-ALL-ALL-008] and the NHSGGC Complaints Policy [ECD-AL-POL-005] detail how complaints are handled, with the aim of satisfying the complainant whilst at the same time being fair and open with all those involved.

Service users unhappy with the Department’s response to a complaint, or where they would prefer to discuss the matter with someone not directly involved with the department or issue raised should contact the NHSGGC Complaints Team by telephone, email or by writing to them. Details about this service are available on the NHSGGC website. If still not satisfied with the response or resolution they then have the opportunity to refer the issue to the Ombudsman.

# Identification and Control of Nonconformities (4.9)

To provide a comprehensive and systematic approach towards corrective and preventative action (CAPA) [MAP-ALL-ALL-007] describes the procedures and responsibilities for the reporting of non-conformance, incidents and subsequent review using the Q-Pulse Audit and Non-Conformance Modules and the DATIX incident reporting application. Procedures specific to the use of the Q-Pulse non conformance module are described in [LWI-ALL-ALL-034]. All non conformances for all locations are reviewed in the quality meeting. All clinical incidents for all locations are reported via the DATIX application and are reviewed at the incident meeting.

# Corrective Action (4.10)

The department reports corrective action as part of its risk and incident management policy [MAP-ALL-ALL-007] using the non conformance module in Q-Pulse or the DATIX application. All corrective actions are discussed in the quality meetings or incident meetings as part of the review of the non conformance or incident. Procedures specific to the use of the Q-Pulse non conformance module are described in [LAP-ALL-ALL-023].

## Root Cause Analysis (4.10b, 4.11b)

To aid in Root Cause Analysis and the recording of Root Cause Analysis there are two forms available [QAC-ALL-ALL-020] and [LAF-ALL-ALL-021]. Procedures specific to the recording of RCA in the Q-Pulse non conformance module are described in [LAP-ALL-ALL-023]. All RCA’s are discussed in the quality meetings or incident meetings as part of the review of the non conformance or incident.

# Preventative Action (4.11)

The department reports preventative action as part of its risk and incident management policy [MAP-ALL-ALL-007] using the non conformance module in Q-Pulse or the DATIX application. All corrective actions are discussed in the quality meetings or incident meetings as part of the review of the non conformance or incident. Procedures specific to the use of the Q-Pulse non conformance module are described in [LAP-ALL-ALL-023].

# Continual Improvement (4.12)

Quality Indicators and Performance Assessment are broken down into pre-analytic, analytical, and post-analytical phases as a framework for the internal audit program, for the assessment of service Quality and Improvement for all locations and the setting of Quality Objectives and Plans. These audits are recorded in the Q-Pulse audit module. The document [MAP-ALL-ALL-004] contains the details of the processes and how findings are reported.

In addition a pre-general staff meeting may be held when required for non senior staff to discuss and formulate suggestions, or ask for clarification of actions and events that affect the service. These are then raised at the General Staff Meeting.

# Control of Records (4.13)

The Department utilises a procedure for the identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records [MAP-ALL-ALL-002, MAP-ALL-ALL-019 and MAP-ALL-ALL-003] to ensure that records are created concurrently with the performance of each activity that may affect the quality of the examination.

# Evaluation and Audits (4.14)

## Review of Requests, Procedures and Sample Requirements (4.14.2)

All equipment and processes are reviewed annually with a summary report [LAF-ALL-ALL-020] attached to its record in the Q-Pulse asset module. These are then made available for discussion and review at the AMR.

## User Feedback (4.14.3)

This is achieved through user liaison (informal and formal), meetings, discussions, communications, and from user surveys performed as part of the departmental audit activity. User needs and requirements including complaints are routinely discussed at the departmental Quality Meeting as a standing agenda item [SCM-MIN-QM-001 onwards]. User needs are formally evaluated and requirements are translated into objective setting and planningwithin in the Quality Management System. User requirements are also discussed at departmental Senior and General Staff Meetings when appropriate [SCM-MIN-SSM-001 onwards and SCM-MIN-GSM-001 onwards]. Summary reports relating to user requirements, associated performance objectives and improvements form a standing agenda item at the Annual Management Review Meeting.

## Staff Suggestions (4.14.4)

Prior to general staff meetings staff may hold an informal meeting when required to discuss points and suggestions to be raised at the general staff meetings [SCM-MIN-GSM-001 onwards]. A box for the “posting” of improvement suggestions is also provided.

## Internal Audit (4.14.5)

The Quality Manager in co-ordination with the senior staff is responsible for scheduling and coordination of internal audits and for ensuring that audits have been conducted in accordance with defined procedures and covers the implementation of the QMS over all locations.

The Departmental Policy details [MAP-ALL-ALL-004] procedures for audit that ensure: internal audit is conducted where practical by personnel trained in audit technique and by personnel independent of the area or process being audited.

The departmental internal audit programme is detailed in [MAP-ALL-ALL-004] and includes the following areas:

* The Pre-analytical processes
* The Post Analytical Processes
* The Analytical Processes
* Training and Competency records
* Any Referral Services
* Quality Control and Quality Assurance program
* The Organisation
* Document Control
* Records
* Accommodation and Environment
* Health and Safety
* BSQR requirements

A series of standardised checklists are used to provide a structure for the audit [QAC-ALL-ALL-001,

QAC-ALL-ALL-002, QAC-ALL-ALL-003, QAC-ALL-ALL-004, QAC-ALL-ALL-005, QAC-ALL-ALL-007, QAC-ALL-ALL-010, QAC-ALL-ALL-011, QAC-ALL-ALL-013, QAC-ALL-ALL-021, QAC-ALL-ALL-025, QAC-ALL-ALL-026, QAC-ALL-ALL-027, QAC-ALL-ALL-028, QAC-ALL-ALL-029, QAC-ALL-BTS-001, QAC-ALL-BTS-004, QAC-ALL-BTS-009].

In addition there are templates that allow for the reporting of other audit types. Horizontal Audits [QAC-ALL-ALL-031], Vertical audits [QAC-ALL-ALL-030], Examination Audits [QAC-ALL-ALL-032], Non Conformance Follow up Audits [QAC-ALL-ALL-035] and auditing of examination turnaround times [QAC-ALL-ALL-033].

Together they allow for comprehensive audit of all processes and activities within in the department.

## Risk Management (4.14.6)

The department evaluates the impact of its work processes and potential failures on examination results and modifies processes when required to reduce or eliminate the identified risks, any decisions and actions taken are documented.

This is managed by the monitoring and recording of incidents on DATIX and by the monitoring and recording of non conformance in Q-pulse. Non conformance and incidents are monitored on a regular basis by the fortnightly incident meeting [SCM-MIN-INC-001 onwards] the monthly Quality meeting [SCM-MIN-QM-001 onwards] and additionally the Laboratory Medicine Clinical Governance meeting. See sections 3.2.7.1.2 and 3.2.7.2.2.

## Quality Indicators (4.14.7)

The Department is committed to the continual improvement of the Laboratory Services.

All Laboratory processes are continually monitored and where necessary corrective and preventive action is taken. The laboratory has established quality indicators identifying key performance indicators such as turnaround times. The KPI’s are reviewed at quality meetings [SCM-MIN-QM-001 onwards], senior staff meetings [SCM-MIN-SSM-001 onwards], Haematology Management Team meetings [SCM-MIN-INC-001 onwards] and the management annual review [SCM-MIN-AMR-001 onwards].

## Reviews by External Organisations (4.14.8)

The department is subject to visits from external accreditation and regulatory bodies. These include UKAS and the MHRA. All visits and any required corrective and/or preventative actions required are recorded in Q. Pulse as non conformances.

# Management Review (4.15)

The Laboratory management team conduct an annual review of the Laboratories Quality Management System and all the services it offers [QMS-ALL-ALL-001 and SCM-MIN-AMR-XXX].

## Review Input (4.15.2)

The input to the management review includes information from the following:

* A review of requests and continuing suitability of procedures and sample requirements.
* The assessment of user feedback.
* Staff suggestions
* Internal audits
* Risk management
* Quality indicators
* Any reviews by external organizations.
* Performance in EQA
* Complaints
* The performance of suppliers
* The Identification, review and control of nonconformities.
* The Identification, review and control of Incidents.
* Continual improvement
* Follow-up actions from previous management reviews.
* Any changes in the volume and scope of work, personnel, and premises
* The management system
* Any recommendations for improvement.

Records of the review are kept and objectives set for the following 12 months [QMS-ALL-ALL-001 and SCM-MIN-AMR-XXX].

## Review Activities (4.15.3)

This includes the assessment of opportunities for improvement and the need for any changes to the

quality management system. This includes updating the quality policy [MAP-ALL-ALL-014] and quality objectives [MAI-ALL-ALL-073] and evaluating the laboratories contribution to patient care.

## Review Output (4.15.4)

The conclusions from the management review will be incorporated into a document that surmises any decisions made and actions agreed in relation to the following:

* The improvement of the effectiveness of the quality management system.
* The improvement of services to users.
* Any identified resource needs.

Actions will be implemented within an agreed time scale. The results of evaluations and processes will available to staff and users [QMS-ALL-ALL-001 and SCM-MIN-AMR-XXX].

# Personnel (5.1)

The department follows NHS Greater Glasgow and Clyde personnel management policies and procedures for staff recruitment and selection, grievance procedures and staff disciplinary action. [ECD-ALL-POL-011, ECD-ALL-POL-012, ECD-ALL-POL-015, ECD-ALL-POL-016, ECD-ALL-POL-17, ECD-ALL-POL-022]. In addition the department has a personnel policy that surmises’ the most relevant points in these policies [MAP-ALL-ALL-018].

Records are located in the personnel files of each staff member, on Q-Pulse and in the eKSF system.

These include:

* Personal details
* Job description
* Terms and conditions of employment
* Staff induction checklist.
* Educational and Professional qualifications
* HCPC registration number.
* Joint annual review.
* Absence record
* Record of disciplinary action.
* Record of training and competency assessments
* Contract of employment

## Personnel Qualifications (5.1.2)

References, Educational and Professional qualifications are required to be vetted at interview and copies if relevant are found in the staff members personnel file.

## Job Descriptions (5.1.3)

Each member of staff has a job description [MAI-ALL-ALL-093, MAI-ALL-ALL-094, MAI-ALL-ALL-095, MAI-ALL-ALL-096, MAI-ALL-ALL-097, MAI-ALL-ALL-098, MAI-ALL-ALL-099, MAI-ALL-ALL-100, MAI-ALL-ALL-119, MAI-ALL-ALL-120 and MAI-ALL-ALL-124] which includes:

* Their Job title
* Their location within the organisation
* To whom they are Accountable
* The main purpose of the job
* A description of duties and responsibilities
* A requirement to participate in staff annual joint review
* A requirement to participation in a CCPD scheme relevant to their role

Each member of staff is given a copy of their job description upon starting. A copy is retained in their personnel file.

## Personnel introduction to the organizational environment (5.1.4)

All new staff members must undertake the corporate and local induction programmes detailed in [ECD-ALL-POL-010, MAF-ALL-ALL-004] in addition all Biomedical Support Workers must complete the Healthcare Support Workers Handbook [TD-NGS-ALL-065] and acknowledge the healthcare support workers code of conduct [ECD-ALL-POL-033]. All grades of staff are expected to complete the relevant GMP modules on learn Pro.

## Training (5.1.5)

Training and Education is delivered in accordance with the policies of NHSGGC, guidelines from relevant professional and registration bodies and the departmental training policy [MAP-ALL-ALL-026].

All staff are given the opportunity for further education and training in relation to the needs of the service and their professional development.

Staff have access to continuing education and training including online sources such as Learnpro in-house training and appropriate training and competency programmes.

Staff are expected to be part of a Continuing Professional Development (CPD) scheme and are encouraged to record their CPD on Q-Pulse [LAP-ALL-ALL-008].

All senior biomedical scientist staff are required to act as mentors and supervisor staff in training whilst they are with them.

There is a training manager and Standard training plans for staff are designated and attached to their Q-Pulse record [LAP-ALL-ALL-023 and LAP-ALL-ALL-008].

Staff have access to a designated study room and are given time for activities that include:

* Completion of the Certificate of Competence for HCPC registration of trainee BMS’
* Completion of the IBMS Specialist Diploma
* Statutory and Mandatory training
* Access to the library and information services
* Attendance at meetings and conferences
* Time for CPD for qualified staff
* Health and Safety
* Departmental Processes
* The QMS

Records are kept of all training and education on their Q-Pulse record.

Athens logins are available to all staff on application.

Financial support may be available for certain activities.

## Competency Assessments (5.1.6)

The department performs competency assessments and has training and competency programmes in place. The standard training and competency programme for each staff member can be found in Q. Pulse in the people module.

Competencies include theoretical assessment and observation of staff as they perform the task.

They include:

* The principles of the test
* The clinical relevance of the test
* Specimen Reception
* The Procedure
* The Storage and retention of samples and records where relevant.
* The equipment and supplies used
* The IQC and EQA associated with the procedure
* The recording and reporting results

## Reviews of Staff Performance (5.1.7)

An annual joint review is held with each staff member and their designated reviewer. All staff performing annual joint reviews have been trained and those staff participating have had a full explanation of the process. The process is recorded using the eKSF system.

The annual joint review includes:

* The objectives and plans for the Laboratory
* The job description of the Staff Member
* Any personal objectives of the Staff Member
* The training and development needs of the Staff Member

## Continuing Education and Professional Development (5.1.8)

All staff are expected to participate in a CPD scheme. Additionally there is a requirement from the registration body (HCPC) that registrants must maintain CPD, they are audited for fitness to practice biennially. To aid them in the maintenance of CPD records staff are encouraged to upload evidence of CPD activities to their record on Q-Pulse [LAP-ALL-ALL-008]. The storing of CPD records on Q-Pulse does not replace membership of a CPD scheme such as that run by the IBMS.

## Personnel Records (5.1.9)

The department holds records of the relevant educational and professional qualifications, training, experience and assessments of each staff member.

Staff records held include:

* Personal details
* Employment details
* Their job description
* The terms and conditions of employment
* Their induction
* Attendance at any mandatory courses
* Their training and competency records
* Their HCPC registration status where relevant
* Joint annual review records
* Their absence record
* A record of disciplinary action
* Any correspondence

These records are held in several different systems.

Staff occupational health records are held within the Occupational Health Department.

# Accommodation and Environmental Conditions (5.2)

The department provides routine and specialised services from 4 sites situated at:

* Glasgow Royal Infirmary
* Gartnavel General Hospital
* Stobhill ACH
* West Glasgow ACH

West Glasgow ACH operates during Haematology clinic hours only.

All services are provided from within purpose built areas. All staff with the exception of those within the Diagnostic Haemato-Oncology service are based at Glasgow Royal Infirmary and all staff report via the structure outlined in section 3.1.4.2. Details of the services provided on each site can be found in the Departmental User Handbook [MAI-ALL-ALL-009].

## Laboratory and Office Facilities (5.2.2)

The laboratory and office facilities are situated within the same area. There is appropriate communication between all areas.

The Laboratory has adequate space for:

* The use and maintenance of equipment
* The performance of all required processes
* Specimen reception
* The separation of incompatible activities
* Staff facilities.
* Ambient and temperature controlled storage facilities.

Access to the Laboratory area is controlled by Identity cards that have been RF chipped and is restricted to Laboratory Staff and other authorised hospital personnel.

Visitors to the Laboratory must be accompanied by Laboratory Staff at all times and must abide by the rules for visitors [LWI-ALL-ALL-031].

## Storage Facilities (5.2.3)

Multiple storage facilities exist with the ability to store all the supplies required for laboratory processes in both ambient and temperature controlled conditions.

Temperature controlled facilities include:

* Cold rooms
* Refrigerators
* Freezers
* Blood Fridges

Where these facilities are used for the storage of blood and blood products or the supplies required to perform blood bank processes these are monitored, maintained and records kept in compliance with the BSQR [ECD-ALL-GDL-028].

A comprehensive remote alarm system is in place for temperature controlled equipment. This system and all temperature controlled storage facilities are maintained and/or calibrated by a supplier who has been accredited to the ISO: 17025 standards.

Additional storage facilities exist for:

* Process and quality records
* Clinical material
* Hazardous substances
* Stationary
* Waste material for disposal

All storage facilities have the appropriate conditions for the maintenance and integrity of samples, reagents, consumables and records.

These facilities are maintained in accordance with national legislation, regulations and guidelines.

Where these facilities are used for the storage of records relating to the issue of blood and blood products or blood bank processes these are monitored and maintained in compliance with the BSQR [ECD-ALL-GDL-028].

## Staff Facilities (5.2.4)

All staff have access to facilities which make provision for personal safety, comfort and hygiene.

They include:

* The provision of toilet and washroom facilities
* The provision of a Staff Room
* The provision of basic catering facilities and/or catering vendors
* The access to drinking water and/or catering vendors
* The provision of secure lockers for the storage of personal effects
* The provision of storage for protective clothing

At GGH and GRI within the department there are conference/seminar rooms available for meetings and training events.

There is a study room at GRI with printing and internet facilities.

## Patient Sample Collection Facilities (5.2.5)

Patient samples are taken in wards, outpatient clinics and in primary care, in general practice and by community staff. These facilities and the staff taking patient samples are not controlled by the department.

Advice on sample types, labelling requirements and other relevant information is available in the departmental users handbook [MAI-ALL-ALL-009].

## Facility Maintenance and Environmental Conditions (5.2.6)

The laboratories are maintained to provide a functional and safe work environment. All work areas are kept clean and well maintained, any deficiencies are reported using the online reporting facility for GGH, GRI and WACH or by telephone to the contracted supplier at STB.

The laboratory monitors and records environmental conditions as required by the BSQR [ECD-ALL-GDL-028] and other guidelines so that these do not invalidate the results or adversely affect the quality of any process.

In addition all staff are distributed a copy of the health and safety code of practice [HCP-ALL-ALL-001].

# Laboratory Equipment Reagent and Consumables (5.3)

The Diagnostics Directorate, NHSGGC in the form of a “Managed Service Contract” is contracted with Abbott Diagnostics together with 3rd Party Supplier Arrangements for the provision of Equipment. This includes maintenance, service and repair, reagents and Consumables. Access to the content of this contract is restricted with access arranged by the General Manager of the Diagnostics Directorate, NHSGGC.

The department via divisional policies complies with national guidelines and NHSGGC policy on purchase, installation, training and safe disposal of all equipment.

The department via divisional policies complies with NHSGGC policy for Standing Orders, Tendering and Contract Procedures and Standing Financial Instructions [ECD-ALL-POL-040] this includes:

* Fair and competitive tendering.
* Value for money.
* Suitability and ease of use.

All equipment within North Glasgow is managed and maintained in accordance with the Management of Laboratory Equipment policy [MAP-ALL-ALL-010] and reagents and consumables to [MAP-ALL-ALL-011].

## Equipment

### Equipment Acceptance Testing (5.3.1.2)

The department verifies equipment prior to use in compliance with the verification policy [MAP-ALL-ALL-031] and management policy [MAP-ALL-ALL-010]. All Equipment and processes must undergo detailed qualification prior to use following the change control and verification procedure [MAP-ALL-ALL-030] and management policy [MAP-ALL-ALL-010]. The results of the acceptance testing are recorded on Q-Pulse [LWI-ALL-ALL-041].

### Equipment Instructions for Use (5.3.1.3)

Standard Operational Procedures and Work Instructions are in place, these describe the safe operation, quality control, quality assurance and maintenance of the equipment and/or process. These are based on the relevant manufacturers recommendations, manuals and appropriate guideline, copies of which may be found on Q-Pulse.

Manufacturer manuals are available.

Training and competency assessment records are in place for equipment and can be located on Q. Pulse with completed records uploaded to the staff member’s record in the people module [LAP-ALL-ALL-008].

### Equipment calibration and metrological traceability (5.3.1.4)

All equipment within North Glasgow is calibrated on a planned basis by competent personnel. This may be by trained local staff or by external suppliers/contractors.

Where relevant, equipment which is calibrated will be labelled to indicate the date of calibration, the due date of the next calibration and initialled by the person responsible for carrying out the calibration.

The frequency of the calibration is based on the following:

* The criticality of the instrument, the system or process it is associated with.
* Any Industry and regulatory requirements
* The recommendations of the supplier/manufacturer

Critical instrumentation will be calibrated every 6 months. Non-critical instrumentation will be calibrated annually. A calibration certificate for the calibrated equipment shall be provided indicting that the test equipment used to carry out the calibration has metrological traceability, a copy will be retained for reference and uploaded to the appropriate record in Q-Pulse in line with management policy [MAP-ALL-ALL-010].

Where these calibrations are for equipment relating to blood, blood products or processes related to the Blood transfusion service compliance with the BSQR [ECD-ALL-GDL-028] is maintained.

Where it is not possible to determine the biological traceability of a process then a biological traceability using appropriate international standards will be performed.

### Equipment maintenance and repair (5.3.1.5)

All equipment has a programme of preventive maintenance which at a minimum follows the manufacturer/supplier’s recommendations. Records of preventive maintenance are kept against the relevant equipment record in the asset module of Q-Pulse in line with management policy [MAP-ALL-ALL-010].

The schedule of preventive maintenance of equipment is carried out by the manufacturer or service supplier as detailed in the maintenance contracts or the MSC with the MSC supplier.

These contracts are reviewed annually taking into account the quality of service provision.

Any Preventive maintenance carried out by laboratory staff is done according to the manufacturers/supplier’s recommendations.

Any defective equipment is immediately withdrawn from service and clearly labelled to show that it must not be used. Checks are made to assess if the defective equipment has had any impact upon examinations undertaken prior to the defect being discovered. If it is determined that there may have been a potential affect then suitable corrective action(s) are undertaken. Upon repair of the equipment verification checks are made to ensure that it is performing in an acceptable manner prior to its return to routine use.

Where this involves equipment relating to blood, blood products or processes related to the Blood transfusion service compliance with the BSQR [ECD-ALL-GDL-028] is maintained.

An authorisation to workform [LAF-ALL-ALL-004} must be completed prior to an engineer commencing work on any equipment.

### Equipment adverse incident reporting (5.3.1.6)

Adverse incidents associated with the use of equipment are recorded as nonconformities using the Non conformance or Asset Modules of Q-Pulse these are assessed for trends at the quality meetings. In addition any equipment failures which have resulted in the release of incorrect results must be logged via the Datix reporting system. A serious equipment failure or trend(s) that indicate equipment issues must be alerted to the equipment supplier and also to the MHRA (for compliance with the BSQR [ECD-ALL-GDL-028]) or HSE if necessary.

### Equipment Records (5.3.1.7)

Records for equipment that is located within North Glasgow are kept on the “Asset” Module of Q-Pulse, supplier details are within the “suppliers” module. Manuals and other documentation are assigned a unique identifier and version number in Q-Pulse but due to the nature of some of the material it is not possible to store them on Q-Pulse. Verification documents and data are stored within the document module of Q-Pulse [LAP-ALL-ALL-023]. This is all in line with management policies [MAP-ALL-ALL-002, MAP-ALL-ALL-010 and MAP-ALL-ALL-030]

As a minimum these records include the following:

* The Identity of the equipment.
* The manufacturer’s name,
* The model
* The serial number.
* A unique equipment number.
* The contact information for the equipment supplier.
* The date of receipt into the laboratory (if known).
* The date the equipment entered into use (if known).
* The location of the equipment.
* The equipment condition when received
  + New
  + Used
  + Reconditioned.
* Any manufacturer’s instructions
* Any records that confirm the equipment’s initial acceptability for use.
* All unscheduled Maintenance records.
* All preventative maintenance records.
* Any Performance records that confirm the equipment’s ongoing acceptability for use.
  + Calibration reports/certificates.
  + Verification data including dates, times and results.
  + Date of next calibration and / or verification.
  + Record of any damage.
  + Record of malfunction.
  + Record of modification.
  + IQC performance
  + EQA performance
  + Annual Review

Where this involves equipment relating to blood, blood products or processes related to the Blood transfusion service compliance with the BSQR [ECD-ALL-GDL-028] is maintained.

## Reagents and Consumables (5.3.2)

The Department operates procedures for the selection, purchasing and ordering of materials. Also for the reception, storage, acceptance testing, and inventory management for laboratory reagents and consumables [MAP-ALL-ALL-011] these procedures are applied across all sites.

This includes

* The assessment of suitability (acceptance testing).
* The receipt of goods.
* The safe storage and issue of records.
* The safe disposal of materials.

### Reception and storage (5.3.2.2)

On receipt items are checked to ensure that the delivery matches the original order and that the goods are received in acceptable condition. Delivery notes can be electronically accepted in the CIMS system. Materials are stored in accordance with the manufacturer’s instructions in designated secure areas at appropriate temperatures. Temperature monitoring of storage areas is carried out where necessary. New deliveries of reagents and kits are verified as being acceptable before use.

### Acceptance testing (5.3.2.3)

New batches of reagents or kits which have a change in formulation or procedure are verified for performance before they are used in routine service [LAP-ALL-COA-006, LWI-ALL-HAE-010, LWI-GGH-ONC-034 and LWI-GRI-BTS-044]. A similar approach is adopted for changes in consumables that may affect the quality of examinations.

### Inventory management (5.3.2.4)

Details relating to the stock control of consumables, reagents, calibration and quality control materials are defined within individual section procedures.

### Instructions for use (5.3.2.5)

Instructions for use are readily available for all reagents these can be found in the individual SOP’s or the manufacturer’s package inserts.

### Adverse incident reporting (5.3.2.6)

Suppliers are assessed on an ongoing basis using the quality management system. Complaints or non-conformities including Field Service Notices will be raised as a non conformance on Q-Pulse against the supplier, trend analysis will be performed and reported at the quality meetings.

### Records (5.3.2.7)

The department maintains records of reagents and consumables in line with [MAP-ALL-ALL-011 and MAP-ALL-ALL-002]

## Risk register

A local risk register is maintained of equipment and reagents that have no alternative within the North Glasgow Sector (MAF-ALL-ALL-051). Risk and Mitigation of the effects of failure are recorded. This risk register is a standing item for review on the Senior Staff Meeting agenda. Additionally any failure or performance issues would be reported via the non conformance reporting system and reviewed at the Quality Meetings.

# Pre-examination Processes (5.4)

## Information for patients and users (5.4.2)

Information for service users is provided in the service user handbook for the department of haematology [MAI-ALL-ALL-009] with access to NHSGGC users via StaffNet and electronic copies available on request for others.

This includes:

* The location of the laboratory sites;
* The types of services offered by the laboratory sites.
* The examinations referred to other laboratories;
* The opening hours of the laboratory sites.
* The examinations offered by the laboratory sites.
* Information on samples
  + Type required
  + Primary sample volumes
  + Special requirements
* The Turnaround times
* The Biological reference intervals (reference ranges).
* The instructions for completion of a manual request form.
* The requirements for the transportation of samples.
* Any requirements for patient consent (if appropriate).
* The laboratory’s criteria for accepting and rejecting samples.
* A list of factors known to significantly affect the performance of the examination.
* A list of factors known to significantly affect interpretation of the results.
* The Uncertainty of Measurement Estimation for quantitative results (UoM)
* The availability of clinical advice on:
  + The ordering of examinations.
  + The interpretation of results.
* The laboratory’s compliance with the policy on data confidentiality.

## Request form information (5.4.3)

The manual request form and electronic requesting includes the following items:

* The unique identification of the patient.
  + Full name
  + Hospital Case Reference Number (CRN)/Community Health Index (CHI) number
  + Date of birth
* The identification and the location of the requestor
* The Date and time of specimen collection
* The type of specimen
* The investigations requested Relevant clinical information
* identification of priority status
* Laboratory number
  + Added to the form in the laboratory

The date and time of specimen receipt by the laboratory is:

* Recorded on the LIMS
* Time Stamped on the request form

Information for service users for the completion of the request including sample type and volume is provided in the service user handbook for the department of haematology [MAI-ALL-ALL-009].

## Primary sample collection and handling (5.4.4)

The General Manager, Diagnostics, NHSGGC is nominally responsible for the implementation and maintenance of processes for laboratory specimen collection, inclusive of the training and management of clinical staff. This includes Phlebotomy Staff. Laboratory staff do not participate in sample collection or transportation.

### Instructions for pre-collection activities (5.4.4.2)

Information for service users for the completion of the request (manual or electronic) including sample type and volume is provided in the service user handbook for the department of haematology [MAI-ALL-ALL-009]. Information is also displayed on the Trakcare system.

### Instructions for collection activities (5.4.4.3)

Information for service users for the completion of the request (manual or electronic) including sample type and volume is provided in the service user handbook for the department of haematology [MAI-ALL-ALL-009]. Information is also displayed on the Trakcare system and advice is available from the laboratory. Electronic requesting automatically captures the required information. NHSGGC policies on Waste Management and Disposal of Sharps control the disposal of material used in sample collection [ECD-ALL-POL-039].

## Sample transportation (5.4.5)

There is an established NHSGGC policy for the transportation of specimens by porters and couriers [ECD-ALL-POL-031] in compliance with regulatory requirements and includes:

* The effective use of the pneumatic tube system
* Ensuring the safety of:
  + The courier
  + NHSGGC Staff
  + The general public
  + The receiving Laboratory
* Instructions for:
  + Packaging
  + Labelling
  + Dispatch
* Reporting incidents during transportation that may:
  + Affect quality of the specimen
  + Affect the safety of personnel

## Sample reception (5.4.6)

The department follows a procedure for specimen reception [LAP-GRI-ALL-002] that includes:

* The accurate identification of the request and specimen
* The registration of the request form and specimen information into the laboratory computer
* The process for handling urgent specimens

The department has a procedure for the reporting of problems with samples [MAP-ALL-ALL-020]

## Pre-examination handling, preparation and storage (5.4.7)

SOP’s detail the procedures for ensuring patient samples avoid deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

# Examination Procedures (5.5)

## Selection, verification and validation of examination procedures (5.5.1)

The Departmental Change Control and Verification Policy [MAP-ALL-ALL-030] and associated documents describe the procedures and requirements for Change Control and the evaluation and performance of validation and/or verification of processes. All data is uploaded to Q-Pulse.

### Verification of examination procedures (5.5.1.2)

The Departmental Change Control and Verification Policy [MAP-ALL-ALL-030] and associated documents describe the procedures and requirements for Change Control, evaluation and performance of the verification of processes.

This includes:

* Any specimen requirements
* The appropriate equipment and supplies
* Any required reagents, standard(s) and/or calibrants
* IQC
* EQA
* Calibration requirements
* Instructions for use
* Any limitations of the process
* Any interference with the process.
* Any Cross reactions with the process.
* The reportable intervals of the examination.
* The recording and calculation of results (if appropriate).
* The Reference limits (reference range).
* Any Hazards and safety precautions (risk assessment).
* The performance criteria .
* The Uncertainty of Measurement estimation.

### Validation of examination procedures (5.5.1.3)

The Departmental Change Control and Verification Policy [MAP-ALL-ALL-030] and associated documents describe the procedures and requirements for Change Control and the evaluation and performance the validation of processes. All data is uploaded to Q-Pulse.

### Measurement uncertainty of measured quantity values (5.5.1.4)

Uncertainty of measurement estimations have been determined [MAP-ALL-ALL-012]. Using the methodology in the UKAS publication UKAS 3003: The Expression of Uncertainty and Confidence in Measurement [ECD-ALL-GDL-059]. These are calculated using a spreadsheet showing bias and targets. They are stored in Q-Pulse and for quantitative assays are recorded in the service user handbook for the Department of Haematology [MAI-ALL-ALL-009] to be available to service users. The estimation of uncertainty of measurement estimation is considered fit for purpose following final review by a clinical member of the Haematology staff to indicate that the uncertainty of measurement estimation would not affect the decision by a service user at any clinical decision value or level, or the advice given by a a Clinical member of the Haematology staff. This is because the clinical decision level/value can vary on an individual basis for all but a few assays. The Uncertainty of measurement for qualitative assays is stored in Q-Pulse and is available on request to the Quality Manager.

## Reference Ranges and Clinical Decision Values (5.5.2)

The reference ranges are included in the standard operating procedures and in the service user handbook for the department of haematology [MAI-ALL-ALL-009] to be available to service users.

## Documentation of examination procedures (5.5.3)

All methods and equipment have standard operating procedures these and any associated work instructions are stored in Q Pulse. These are all controlled documents which are reviewed biennially or sooner as stated on the document. The requirements are described in the policy document [MAP-ALL-ALL-003] the process in [LAP-ALL-ALL-008].

# Ensuring quality of examination results (5.6)

The Departmental Quality Assurance Policy [MAP-ALL-ALL-012] outlines the department’s procedures for quality Assurance.

## Quality Control (5.6.2)

### Quality control materials (5.6.2.1)

Instructions on the preparation for use, stability and storage are contained in the individual SOP’s.

Low, mid and high value controls are used at all locations where available. The levels are selected to check the assay for linearity, to test the functional limit of detection and to check the assay at the most frequently measured interface between normal and pathological values. The Frequency of performing of IQC is dependent on analyser and/or method stability as well as continuous processing or batch analysis.

### Quality control data (5.6.2.2)

IQC reports for all locations are discussed monthly at the quality meeting [SCM-MIN-QM-001 onwards]. Where possible IQC data is uploaded onto the relevant asset record. There are procedures in place for the assessment of the impact of IQC failure including, re-analysis of samples, amending reports and incident reporting.

## Interlaboratory comparisons (5.6.3)

The Departmental Quality Assurance Policy [MAP-ALL-ALL-012] outlines the department’s procedures for quality Assurance.

### Participation (5.6.3.1)

The department participates in all appropriate EQA schemes that are accredited to ISO:17043 where these are available. EQA is undertaken at all the laboratory sites within North Glasgow and performance reported at the Quality Meeting [SCM-MIN-QM-001 onwards]. Reports are available on Q-Pulse.

### Alternative approaches (5.6.3.2)

The IQC data is available for all the analysers across all locations in North Glasgow and is compared routinely as part of the IQC review process. Cross site sample checks are performed if required.

### Analysis of Interlaboratory comparison samples (5.6.3.3)

All samples received from EQA schemes are processed as if they were patient samples by the same personnel responsible for performing the process routinely.

### Evaluation of laboratory performance (5.6.3.4)

Lab performance for all locations is communicated and assessed at the Quality meetings [SCM-ALL-ALL-XXX]. Discussion is based on IQC and EQA performance for possible systematic and random errors in performance. Cross site review is included. Problems are highlighted, decisions minuted and actions agreed. Performance that is out with consensus is raised as a non conformance in Q-Pulse.

## Comparability of examination results (5.6.4)

Cross site analysis is performed for all those tests performed on more than one site as detailed in the Quality Assurance Policy [MAP-ALL-ALL-012]. This is discussed at the quality meeting [SCM-ALL-ALL-XXX] and used in the annual review of processes. The data obtained is available on Q-Pulse.

# Post-examination processes (5.7)

## Review of results (5.7.1)

The department has individual documented processes for the review of examination results before release which include the automatic selection and reporting of results.

## Storage, retention and disposal of clinical samples (5.7.2)

The departments stores, retains and disposes of clinical samples in accordance with the requirements of the Human Tissue Act 2004 [ECD-ALL-MAN-002], guidelines from the Royal College of Pathologists and the Institute of Biomedical Science and NHSGGC policies regarding the retention, storage and disposal of clinical material [MAP-ALL-ALL-002, ECD-ALL-GDL-018 and ECD-ALL-POL-039], and guidance from the Royal College of Pathologists and the Institute of Biomedical Science regarding the Release of Specimens.

# Reporting of results (5.8)

The department has a policy and procedure for the reporting of results that includes communication [MAP-ALL-ALL-020]. Reports are available to all NHSGGC users electronically and to others as a printed copy. All results are reported locally on the site they are generated by suitably qualified staff. This is performed on a single middleware and LIMS platform that covers all sites.

## Reference to Accreditation Standards

The Department chooses not to include the UKAS accreditation symbol on the laboratory hard copy and electronic reports due to technical limitations but to include a reference to accreditation on the department’s website.

“NHSGGC North Sector Haematology Laboratories are an ISO15189 accredited laboratory (UKAS No 9570) for all tests as described within our schedule of scope held on the UKAS website.”

In accordance with UKAS guidance publication Lab 1, Reference to Accreditation for Laboratories, Section 5.1. We choose to inform our users of our accreditation status by including a link to our Schedule of Accreditation held on the UKAS website. This link may be found the laboratory’s website and within the User Handbook. Those tests that are accredited are indicated in the service users’ handbook.

## Report attributes (5.8.2)

The department’s reports communicate the laboratory results and include the following when required:

* Comments on sample quality that might compromise results.
* Comments regarding sample suitability
* The Flagging of critical results
* Interpretive comments on results where relevant.

## Report content (5.8.3)

Reports have been designed to comply with the needs of the users and are available in electronic form to all NHSGGC users and printed copy to certain areas and other users.

Reports include the following:

* The Laboratory performing analysis.
* The unique identity of the patient.
* The requester
* The location (origin) of the request
* The type of specimen
* The date and time of collection
* The time and date of report
* The results
* A comment for the reason if no examination is performed
* The Reference intervals (reference ranges) age and gender specific where appropriate.
* Interpretive comments (where appropriate)
* Any explanatory or cautionary comments about results (where appropriate)
* The highlighting of abnormal results
* Where possible the identification of the person(s) verifying the results and authorising the release of the report.

# Release of results (5.9)

The departmental procedure [MAP-ALL-ALL-020] details the process to be followed.

This procedure includes consideration of the following:

* The indication in the report if the quality of the primary sample received was unsuitable for examination.
* The indication in the report if the quality of the primary sample received could have compromised the quality of the result generated.
* Any checks to ensure that results are without errors in transcription.
* That if an examination result falls within established critical values:
  + A clinician or other authorised health professional is immediately notified.
* That if a result has been communicated verbally the following is recorded:
  + The name of the person notified
  + Details of the results conveyed
  + Any difficulties encountered in making the notification
  + The name of the laboratory member who undertook the communication
  + The date and Time of communication
* That checks are made to ensure that results are only made available to those authorised to receive them.

If results are communicated via telephone then they are only provided to suitably authorised personnel these are then followed up by the production of a formal report.

## Automated selection and reporting of results (5.9.2)

Automated selection and reporting of results is agreed by the reporting clinical staff and is defined at an individual test level as part of the change control and verification process. The reference intervals, action limits and authorisation limits of tests are programmed into both the middleware and the LIMS.

## Revised reports (5.9.3)

There is a departmental procedure [LAP-ALL-ALL-007] for revising and amending reports which includes:

* The criteria for issuing a revised and amended report.
* The identification to the user of issue of an amended or revised report.
* The process for recording the issue of revised and amended reports.
* The reasons for issuing an amended or revised report
* The instigation of corrective and preventive action (if required).
* The accurate recording of revised and amended reports.

# Laboratory information management (5.10)

The department has a documented procedure [MAP-ALL-ALL-019] to ensure that the confidentiality of patient information is maintained at all times this is also in compliance with the BSQR [ECD-ALL-GDL-028] and NHSGGC policy [ECD-ALL-POL-013].

## Authorities and responsibilities (5.10.2)

The authorities and responsibilities of personnel who use the Laboratory Information System (LIMS), including the maintenance and modification of the system are controlled by their access level this restricts those who have the authority and responsibility to do the following:

* Accessing patient data and information.
* The entry of patient data and examination results.
* Modifying or changing patient data or examination results;
* The Validation and reporting and release of examination results
* The Modification of the system

## Information system management (5.10.3)

The LIMS is fully supported by the supplier. It is operated and managed in accordance with the departmental procedures and NHSGGC policies to ensure:

* Data security.
* Controlled access.
* Storage of information.
* Archiving of information.
* Retrieval of information.
* Disposal of information.

The operation of the system is in compliance with data protection legislation, departmental and NHSGGC policies [ECD-ALL-POL-013] and the BSQR [ECD-ALL-GDL-028].

The system is subject to change control and verification [MAP-ALL-ALL-004 and MAP-ALL-ALL-030] and audit.

# Appendices

## Appendix 1: Referenced Documents

ECD-ALL-POL-005: NHSGGC Complaints Policy

ECD-ALL-POL-006: NHSGGC Confidentiality Policy

ECD-ALL-POL-010: NHSGGC Corporate Induction

ECD-ALL-POL-011: NHSGGC Code of Conduct for Staff

ECD-ALL-POL-012: NHSGGC Equality and Diversity Policy

ECD-ALL-POL-013**:** NHSGGC Confidentiality and Data Protection Policy

ECD-ALL-POL-015: NHSGGC Attendance Management Policy

ECD-ALL-POL-016: NHSGGC Employment or Statutory regulated Professionals

ECD-ALL-POL-017: NHSGGC Grievance Policy and Procedure

ECD-ALL-POL-022: NHSGGC Disciplinary Policy

ECD-ALL-POL-023: Header and Footer

ECD-ALL-POL-031: NHSGGC Transport and Disposal of Specimens Containers and Specimens Policy

ECD-ALL-POL-033: Healthcare Support Workers Code of Conduct

ECD-ALL-POL-039: NHSGGC Waste Management Policy

ECD-ALL-POL-040: NHSGGC Standing Financial Instructions

HCP-ALL-ALL-001: Health and Safety Code of Practice

LAF-ALL-ALL-004: Service/Maintenance Engineer - authorisation (permit) to work form

LAF-ALL-ALL-020: Equipment and Process Review form

LAF-ALL-ALL-021: Incident Investigation form

LAP-ALL-ALL-001: SOP Template

LAP-ALL-ALL-007: Amending and Revising Reports

LAP-ALL-ALL-008: Use of the Q-Pulse People and Training Course Module

LAP-ALL-ALL-023: Q-Pulse

LAP-ALL-ALL-033: Contingency plan

LAP-ALL-COA-006: Haemostasis Batch Acceptance Procedure

LWI-ALL-ALL-031: Model Rules for Visitors

LWI-ALL-HAE-010: Routine Haematology Batch Acceptance Procedure

LWI-GGH-ONC-034: Cell Markers Batch Acceptance

LWI-GRI-BTS-044: Product Batch Acceptance

MAF-ALL-ALL-004: Departmental Induction Form

MAF-ALL-ALL-051: Local risk register

MAI-ALL-ALL-009: Departmental Service User Guide

MAI-ALL-ALL-073: Departmental Quality Objectives

MAI-ALL-ALL-093: JD Haemato-oncology Manager

MAI-ALL-ALL-094: JD Haemostasis Manager

MAI-ALL-ALL-095: JD Sector Laboratory Manager

MAI-ALL-ALL-096: JD Quality, Training and POCT Manager

MAI-ALL-ALL-097: JD Biomedical Support Worker - Higher Level

MAI-ALL-ALL-098: JD Senior Specialist BMS

MAI-ALL-ALL-099: JD Specialist BMS

MAI-ALL-ALL-100: JD Technical Manager

MAI-ALL-ALL-119: JD Technical Services Manager

MAI-ALL-ALL-120: JD Associate Practitioner (band 4)

MAI-ALL-ALL-124: JD Consultant Clinical Scientist

MAP-ALL-ALL-001: Management Policy Template

MAP-ALL-ALL-002: The Retention & Storage of Clinical Material, QMS & Pathological Records, Specimens and Archives

MAP-ALL-ALL-003: Control of QMS Documentation

MAP-ALL-ALL-004: Departmental Audit

MAP-ALL-ALL-007: Incident reporting and Risk Management

MAP-ALL-ALL-008: Complaints Policy

MAP-ALL-ALL-010: Management of Laboratory Equipment

MAP-ALL-ALL-011: Management of Supplies, Reagents, Calibration and Quality Control Material

MAP-ALL-ALL-012: Quality Assurance

MAP-ALL-ALL-013: Procedure for the Annual Management Review

MAP-ALL-ALL-014: Departmental Quality Policy

MAP-ALL-ALL-017: Specimen Referral, Transportation and Packaging Requirements

MAP-ALL-ALL-018: Personnel Management

MAP-ALL-ALL-020: Reporting and Communicating of Results

MAP-ALL-ALL-024: Service Level Agreement (SLA)

MAP-ALL-ALL-026: Staff education and Training Policy

MAP-ALL-ALL-030: Change Control and Verification Policy

QAC-ALL-ALL-001: Organisation and QMS Audit

QAC-ALL-ALL-002: Document Audit

QAC-ALL-ALL-003: Pre-Analytical Process Audit

QAC-ALL-ALL-004: Post Analytical Process Audit

QAC-ALL-ALL-005: Equipment, Reagents and Consumables Audit

QAC-ALL-ALL-007: Quality Control/Assurance Audit

QAC-ALL-ALL-010: Accommodation and Environment Audit

QAC-ALL-ALL-011: Training and Competency Audit

QAC-ALL-ALL-013: Personnel Audit

QAC-ALL-ALL-020: 5 Whys Checklist

QAC-ALL-ALL-021: Monthly Fire Audit

QAC-ALL-ALL-025: CA/PA, Validation and Verification Audit

QAC-ALL-ALL-026: Laboratory Information Systems Audit

QAC-ALL-ALL-027: Evaluation, Audit and Review Audit

QAC-ALL-ALL-028: Control of Records Audit

QAC-ALL-ALL-029: Services, Referral and Advice Audit

QAC-ALL-ALL-030: Vertical Audit Form

QAC-ALL-ALL-031: Horizontal Audit Form

QAC-ALL-ALL-032: Examination Audit

QAC-ALL-ALL-033: TAT Audit form

QAC-ALL-ALL-035: Non Conformance Follow up Audit Form

QAC-ALL-BTS-001: Satellite Blood Fridges Audit

QAC-ALL-BTS-004: Traceability of Blood and Blood Products Audit

QAC-ALL-BTS-009: Cold Chain Storage (Satellite) Audit

QAC-ALL-ALL-048: Referral Laboratory Checklist

QM-ALL-ALL-001: Quality Manual

SCM-MIN-AMR-XXX: AMR Minutes

SCM-MIN-GGH-XXX: Haemato-Oncology Meeting Minutes

SCM-MIN-GSM-XXX: General Staff Meeting Minutes

SCM-MIN-HMT-XXX: Haematology Management Team Meeting Minutes

SCM-MIN-HTM-XXX: Haemostasis Team Meeting Minutes

SCM-MIN-HTT-XXX: Hospital Transfusion Team Meeting Minutes

SCM-MIN-INC-XXX: Incident Meeting Minutes

SCM-MIN-QM-XXX: Quality Meeting Minutes

SCM-MIN-SSM-XXX: Senior Staff Meeting Minutes

TD-NGS-ALL-0065: Health care support worker workbook

## Appendix 2: Regulatory and Accreditation Body Publications

ECD-ALL-GDL-027: Medical Laboratories: Requirements for Quality and Competence (ISO 15189: 2012)

ECD-ALL-GDL-028 Blood Safety and Quality Regulations 2005 and Amendment 2007

ECD-ALL-GDL-029: The National Accreditation Logo & Symbols: Conditions for use by UKAS and UKAS accredited organisations (URN BIS 14/902)

ECD-ALL-GDl-031: UKAS Lab 1: reference to Accreditation for Laboratories

ECD-ALL-GDL-032: UKAS Lab 3: The Conduct of UKAS Laboratory Assessments

ECD-ALL-GDL-034: UKAS Lab 12: The Expression of Uncertainty in Testing

ECD-ALL-GDL-036: UKAS Lab 39: UKAS Guidance on the Implementation and Management of Flexible Scopes of Accreditation Within Laboratories

ECD-ALL-GDL-038: UKAS TPS 41: UKAS Policy on Metrological Traceability

ECD-ALL-GDL-039: UKAS TPS 47: UKAS Policy on Participation in Proficiency Testing

ECD-ALL-GDL-042: UKAS TPS 51: Accreditation of Multi-Site/Group Laboratories

ECD-ALL-GDL-044: UKAS TPS 57: Guidance and Policy on the Selection and Use of Reference Materials

ECD-ALL-GDL-046: UKAS TPS 63: UKAS Policy on Deviating Samples

ECD-ALL-GDL-059: UKAS 3003: The Expression of Uncertainty and Confidence in Measurement

ECD-ALL-GDL-065: The Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments 2005 and 2006

ECD-ALL-GDL-071: JACIE Standards

ECD-ALL-GDL-073: Data Protection Act 2018

ECD-BTS-GDL-013: MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2015

ECD-ALL-MAN-002: Human Tissue Act – 2004

## Appendix 3: Quality Policy

