**QUALITY MANUAL**

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# Abbreviations and Acronyms

|  |  |
| --- | --- |
| CSM | Clinical Services Manager |
| AMR | Annual Management Review |
| BSQR | Blood Safety and Quality Regulations |
| CPD | Continuing Professional Development |
| EQA | External Quality Assessment |
| HCPC | Health and Care Professions Council |
| HMT | Haematology Management Team |
| HSE | Health and Safety Executive |
| HTC | Hospital Transfusion Committee |
| HTT | Hospital Transfusion Team |
| 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 |
| QEUH | Queen Elizabeth University Hospital |
| QM | Quality Manual |
| QMS | Quality Management System |
| RCA | Root Cause Analysis |
| RF | Radio Frequency |
| RHC | Royal Hospital for Children |
| SABRE | Serious Adverse Blood Related Events |
| SLA | Service Level Agreement |
| SLM | Sector Laboratory Manager |
| SNBTS | Scottish National Blood Transfusion Service |
| SOP(s) | Standard Operating Procedure(s) |
| SSM | Senior Staff Meeting |
| TP | Transfusion Practitioner |
| TSM | Technical Services Manager |
| TSSM | Technical Senior Staff Meeting |
| UKAS | United Kingdom Accreditation Service |
| VACH | New Victoria Ambulatory Care Hospital |

# 1. Introduction

This Quality Manual, together with the Policy and Procedure documents which are referenced, describes the Quality Management System of the Department of Haematology, South Glasgow Sector, NHSGGC. This Quality Manual has been created to meet with all of the requirements of The International Standard ISO 15189:2022 Medical Laboratories - Requirements for Quality and Competence (and all associated documentation) (hence known as ISO:15189), Blood Safety and Quality Regulations (2005 and subsequent amendments) (hence known as BSQR), and other appropriate national and international standards.

Sections 4 - 8 of this Quality Manual are arranged to equate with BS EN ISO 15189:2022 Medical laboratories – requirements for quality and competence. After the title of each section or sub section, the relevant standard is referenced in brackets. 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 in **BOLD.** All referenced documents can be found on the department’s QMS Q-Pulse. All the policies and procedures referenced are mandatory within the Department of Haematology, South Glasgow Sector.

# 1.1 Overview of the organization

As part of the diagnostic services of NHSGGC, the Department of Haematology South Glasgow Sector provides haematology services relevant to service users for the benefit of the patients and population at Queen Elizabeth University Hospital Glasgow, Laboratory Medicine Building and The Victoria Ambulatory Care Hospital satellite laboratory. Information on services provided at each site can be found on our website [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

The laboratory has implemented 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, recording these instances so that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers.

# 1.2 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.

# 2. Objectives

The objectives of the laboratory are to produce accurate, reliable and timely analyses' results, achieve and maintain an effective quality management system, and to ensure compliance with relevant statutory and safety requirements in accordance with **SG-MPOL-035** – Quality Policy

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

# 2.1 Scope

This quality manual describes the quality management system scope of the Department of Haematology, South Glasgow Sectoras follows:

* **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 will facilitate the implementation of the quality management system as well as ensure its maintenance and required updates during altering circumstances. This should also allow effective communication and 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 measures of compliance with quality.

# 3. Quality Policy Statement

Senior management are 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, understood and adhered to by all employees. The laboratory ensures a competent workforce to deliver quality results in a timely manner according to ISO 15189 and the BSQR. The laboratory ensures that each section participates in and records internal quality control and assurance activity. The laboratory ensures that each section participates in appropriate External Quality Assurance schemes with evidence of performance review. The laboratory ensures that each section is routinely active in addressing Health & Safety, Staff training and development, appropriate equipment maintenance and internal audit.

# 4. General requirements

## 4.1 Impartiality (ISO 4.1 a-e)

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. NHSGGC workforce policies **SG-REF-G009** NSS Conduct Policy, **SG-REF-G049** NSS Conduct Guide to expected standards of behaviour and **SG-REF-G012** NHS GGC equality, diversity and human rights policy outlines the ethical conduct expected of staff.

It is the responsibility of staff to ensure that they do not place themselves in a position which

risks, or appears to risk, conflict between their private interests and their NHS duties therefore all staff are required to adhere to **SG-REF-G055** NSHGGC Finance Code of Conduct, which is incorporated into the standard contract of employment for all staff.

In accordance with **SG-MPOL-011** Policy and Procedures for the Procurement and Management of Equipment and **SG-MPOL-013** Policy and Procedures for the Procurement and Management of Reagents, Calibration and Quality Control Material, all personnel involved in any procurement process must complete a declaration of interest form. These completed forms will be stored in Q-Pulse (**SG-MREC-097** Declaration of Interest Forms) and will be reviewed annually. If there is evidence of impartiality, all procurement and approver rights will be removed.

## 4.2 Confidentiality (ISO 4.2.1 – 4.2.3)

Laboratory management ensures there are appropriate procedures to ensure ethical respect of patient samples and confidentiality of patient information. This is described in the following documentation:

* **SG-MPOL-005** - Policy and procedure for control of clinical material – section 5.3.6 describes release of specimens to 3rd parties
* **SG-MPOL-012** - Policy and Procedure for the Management of IT Systems, Electronic Data and Information
* **SG-EXT-G019** - NHSGGC Confidentiality Policy
* **SG-REF-G009** - NSS Conduct policy
* **SG-REF-G024** - RCPath Guidelines on the retention and storage of pathological records and archives

Staff training around confidentiality is part of the NHSGGC Statutory and Mandatory training programme as described in **SG-MPOL-008** Training Policy and all staff are required to complete the statutory mandatory LearnPro module GGC: 009 Safe Information Handling.

## 4.3 Requirements regarding patients (ISO 4.3 a - i)

The needs and requirements of users are translated into requirements, which form the focus of objective setting and planning. The needs and requirements of users are kept under constant review, achieved through regular scheduled meetings, informal discussion and communication, and from user surveys (when deemed necessary). The quality manager also attends the Paediatric Haematology Governance Meetings, and, when requested, the Paediatric Intensive Care Unit Incident Meetings, to discuss any user concerns or suggestions.

Assessment of user satisfaction, complaints and suggestions is reviewed monthly at the quality group meetings as a standing agenda item. Any suggestions are registered via the non-conformance module on Q Pulse. These are discussed, and the outcomes recorded in the minutes and against the N-C Record.; these form part of the annual management review.

Information for users is contained in **SG-MPOL-039** user handbook, accessible viathe laboratories’ NHSGGC South Sector Haematology webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

* **SG-MPOL-047** Policy and Procedures for Staff and User Suggestions describes the process of recording, evaluating and providing feedback on staff and user suggestions. The need of users are reviewed at regular meetings with outcomes recorded in the minutes (**SG-MREC-071** technical senior staff meetings) (**SG-MREC-037** BMS general staff meetings), (**SG-MREC-039** – quality management meeting) and against the non-conformance record in Q-Pulse. Assessment of user satisfaction, complaints and suggestions is reviewed monthly at the quality group meetings as a standing agenda item and at Blood Transfusion specific committees (HTT and HTC)
* Examinations are reviewed at the quarterly Senior Staff Meeting (SSM) as a standing agenda item to ensure examinations offered by the laboratory remain suitable
* Incidents, including accidents, near misses and clinical incidents, are discussed at monthly local incident meeting **SG-MREC- 050,** Senior Staff Meetings, Clinical Governance meetings and transfusion specific HTT and HTC (minutes are held on MS Teams) in accordance with **SG-MPOL-045** Incident Management policy and procedure. Feedback is provided to users and staff as appropriate including details of corrective and preventive measures that have been implemented.
* The Department operates within NHSGGC Duty of Candour Policy ([Duty of Candour (scot.nhs.uk)](http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/Pages/DutyofCandour.aspx) as per **SG-REF-G037** NHSGGC Incident Management policy
* Laboratory staff uphold the rights of treating patients and samples with care and respect by adhering to **SG-REF-G009** NSS Conduct Policy and **SG-REF-G049** NSS Conduct Guide to expected standards of behaviour.
* **SG-MPOL-005** Policy & Procedures for the Control of Clinical Material describes use of patient samples for audit and IQC purposes. The majority of our samples are venepuncture therefore in accordance with ISO15189:2022 standard 7.2.4.3, consent is therefore inferred. Informed consent maybe required for Bone Marrow aspirate or Haemoglobinopathy samples, however this is out with the laboratories’ control and the responsibility for obtaining consent lies with the clinician.
* To ensure integrity of retained samples, all samples and results are held in accordance with **SG-MPOL-005** Policy & Procedures for the Control of Clinical Material, and **SG-REF-G024** RCPath guidelines; and **SG-SOP-B048** Traceability in compliance with BSQR 2005. To assess effectiveness of these procedures, sample storage and retrieval is assessed in vertical audits **SG-FORM-G038** and scope audits **SG-FORM-G074.**
* Patients and service users can request information in accordance with **SG-REF-G057** NHS GGC Freedom of Information Policy which is available for user via the NHSGGC website [Freedom Of Information - NHSGGC](https://www.nhsggc.scot/contact-us/freedom-of-information-foi/)
* Laboratory staff uphold the rights of patients to care that is free from discrimination; this is evidenced by completion of the statutory and mandatory Equality, Diversity and Human rights LearnPro module.

# 5. Structural and governance requirements

## 5.1 Legal entity (ISO 5.1)

The laboratories of the Department of Clinical and Laboratory Haematology, South Glasgow Sector, NHSGGC, are a constituent of the Diagnostics Division of the Acute Services of NHS Greater Glasgow and Clyde. The department provides routine and specialised haematology services, together with Blood Transfusion, from QEUH as well as a limited repertoire of tests at the VACH (latter open Mon-Fri 08:45-17:00 only) and the Paediatric Haemato-Oncology Day unit and clinics in RHC (open Mon-Fri 08:45-17:00 only)

QEUH Address:

Department of Haematology and Blood Transfusion

Level 1

Laboratory Medicine and FM Building

Queen Elizabeth University Hospital

1345 Govan Road

Glasgow

G51 4TF

Telephone: 0141-354-9100 Fax: 0141-232-7982

VACH Address:

Laboratories

Clinic P, 2nd Floor

Grange Road,

Glasgow G42 9LF

Telephone: 0141-347-8141

RHC: Correspondence via QEUH site.

# 5.2 Laboratory Director (ISO 5.2.1-5.2.3)

## 5.2.1 Laboratory Director Competence

There is one Laboratory Director for South Sector, Dr Alison Laing, and they report to the Head of Service. Each clinician may have additional duties as outlined in their job description/job plan.

Table 1, section 5.2.3 details the responsibilities and to whom those duties may be delegated.

Competence is demonstrated as per **SG-MPOL-007** Policy and Procedure for Personnel Management, section 5.1.2 Evidence of Training & CPD.

Clinical staff competency will be documented using form **SG-FORM-G068** Annual Medical Staff Laboratory Competency Record. This will be assessed and signed off by the Lead Clinician and uploaded to the training record in Q-Pulse People module.

## 5.2.2 Laboratory Director Responsibilities

The Laboratory Director shall:

a) Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;

b) 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;

c) 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;

d) Ensure the implementation of the quality policy and management system

e) Implement a safe laboratory environment in compliance with good practice and applicable requirements;

f) Ensure that risk management is applied to all aspects of laboratory operation, and the department’s processes for identifying risk to patient harm and identifying opportunities for improvement are evaluated and modified, when identified as being ineffective.

g) Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;

h) Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;

i) Select and monitor laboratory suppliers;

j) Select referral laboratories and monitor the quality of their service;

k) Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;

l) Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

m) Monitor all work performed in the laboratory to determine that clinically relevant information is being generated;

n) Address any complaint, request or suggestion from staff and/or users of laboratory services;

o) 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;

p) Plan and direct research and development, where appropriate.

## 5.2.3 Delegation of duties

Day to day control of each section within the laboratory is under direction of appointed Senior BMS, BMS Team leader and Managers, co-ordinated by the Laboratory Manager and Technical Services Manager (TSM)

The following table details the responsibilities and to whom those duties may be delegated:

**Table 1**. Delegation of duties

|  |  |  |
| --- | --- | --- |
| **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. | Laboratory Director, TSM, SLM and laboratory management team. | Through HMT and MSC budget meetings. |
| 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. | Laboratory Director, TSM, SLM, Quality Manager and TPs | Senior laboratory staff deal directly with UKAS and MHRA. User meetings and SLA’s with outside service users. |
| 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. |
| Ensure the implementation of the quality policy. | Laboratory Director, TSM, SLM, and Quality Manager | Controlled document in QMS. (**SG-MPOL-035**) |
| Implement a safe laboratory environment in compliance with good practice and applicable requirements. | TSM, SLM, and Health and Safety Officer. | H&S committee, relevant items raised at staff meetings and daily huddles.(**SG-MPOL-009**) |
| Application of risk management to all laboratory activities | Laboratory Director, TSM, SLM and Quality Manager | Primary role of TSM, SLM and Quality Manager in accordance with **SG-MPOL-052** Clinical Risk Management policy. |
| Serve as a contributing member of the medical staff for these facilities served, if applicable and appropriate. | Laboratory Director | 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, Technical Leads and Quality Manager | All referral labs are asked to complete evaluation form annually. (**SG-FORM-G034**). UKAS Website is checked quarterly to ensure no sanctions have been applied to the laboratories. |
| **Duty** | **Responsibility** | **Comment** |
| Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations. | TSM, SLM, and Quality/Training Manager | All staff complete mandatory training, NEQAS, CPD, and attend scientific meetings  |
| Define, implement and monitor standards of performance and quality improvement of the medical laboratory service and services. | Laboratory Director, TSM, SLM, Technical leads, Quality Manager, Transfusion practitioner | Defined through quality manual and monitored via balanced scorecard monthly at HMT. (**SG-MPOL-001**) |
| Monitor all work performed in the laboratory to determine that clinically relevant information is being generated. | Laboratory Director, TSM, SLM, Technical Leads and Quality Manager. | Audit module in QMS, Laboratory Non Conformance Logging in Q Pulse, Incident, and quality and HTC meetings. |
| Address any complaint, request or suggestion from staff and/or users of laboratory services. | Laboratory Director, TSM, SLM, Quality manager and Technical Leads | Audit module in QMS, Incident, quality, staff, HMT, HTC meetings and Daily Huddles |
| 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. | Laboratory Director, TSM, SLM, and Technical Leads | (**SG-MPOL-034**)(**SG-EXT-G018**) |
| Plan and direct research and development, where appropriate. | Head of Service, Laboratory Director TSM, SLM, and Technical Leads. |  |

# 5.3 Laboratory Activities (ISO 5.3.1 – 5.3.3)

## 5.3.1 General

Information on the services provided by the laboratory are available in **SG-MPOL-039** user handbook and on the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

The department’s UKAS schedule of accreditation is available on NHSGGC webpage along with link to UKAS website for service users.

## 5.3.2 Conformance with requirements

The organisation and management of the department is detailed below (section 5.4). The department accepts its responsibility to meet the requirements of ISO15189:2022 standards for Medical Laboratories.

## 5.3.3 Advisory Services

The Department provides a comprehensive routine and specialised Haematology, Haemostasis, Blood Transfusion and Haemato-Oncology service to service users within and out with NHSGGC. The Departmental Clinical Team provides a clinical advisory service for service users within 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 **SG-MPOL-039** Service User Handbook which is available for patients and users to access via the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/). This includes:

* Use of the service
* Sample types
* Turnaround Times
* Requesting requirements
* Available examinations.

To facilitate monitoring of sample acceptability criteria, monthly rejected sample data is presented at monthly quality meetings as standing agenda item (**SG-MREC-100**) and a quarterly sample transport audit is performed in accordance with **SG-MPOL-025** Policy and Procedure for Departmental Audits.

# 5.4 Structure and authority (ISO 5.4.1 – 5.4.2)

The department of Haematology and Blood Transfusion is part of the Diagnostic Directorate, within the Acute Services Division of NHS Greater Glasgow and Clyde. The Divisional webpage is [Home - NHSGGC](https://www.nhsggc.scot/).

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 to deliver quality results in a timely manner according to ISO15189 and the BSQR.

The organisation relationships overarching the department are shown in **SG-MREC-108** NHSGGC Laboratory Medicine chart, which provides a high level organisation overview of GGC lab Medicine along with individual lab discipline and sector organisational structure. The diagnostics division and laboratory organisation and reporting structure is shown below:

## Diagram 1. Diagnostics division organisational structure

## Dia**gram 2**. **NHSGGC Haematology South Sector structure**

The tables below show the deputy cover arrangements in place across the department along with post holder responsibilities. Please also refer to **SG-MPOL-007** Policy and Procedure for Personnel Management.

**Table 2**. Named post holders and deputies

|  |  |  |
| --- | --- | --- |
| **Post** | **Post Holder** | **Deputy** |
| **General Manager** | Rob Gardiner | Laura Jane Scott |
| **Clinical Services Manager** | Laura Jane Scott | Tom Moffat |
| **Clinical Head of Service** | Dr Alistair Hart | Consultant Haematology Staff |
| **Laboratory Director** | Dr Susan McNeill | Dr Alison Laing |
| **Technical Services Manager** | Tom Moffat | Maureen McBrearty |
| **Sector Laboratory Manager** | Maureen McBrearty | Tom Moffat |
| **Quality Training and POCT Manager** | Linsay Thomson | Maureen McBrearty |
| **Haemoglobinopathy Manager** | Ian Fergus | Jacqueline Fellowes |
| **Health and Safety Manager** | Maureen McBrearty | Tom Moffat |

**Table 3**. Roles and responsibilities

|  |  |
| --- | --- |
| Sector Laboratory Director | The Sector Laboratory Director 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 (**SG-EXT-G020**) |
| Sector Laboratory Manager | Responsibilities of the Sector Laboratory Manager are defined in **SG-EXT-G021**  |
| Quality, Training and POCT Manager | Responsibilities of the Quality, Training and POC manager are defined in **SG-EXT-G022** |
| Haemo-globinopathy Manager | Responsibilities of the Haemoglobinopathy manager are defined in **SG-EXT-G023** |

# 5.4.2 Quality Management

In accordance with **SG-MPOL-007** Policy and Procedure for Personnel Management, NHSGGC Haematology South Sector has appointed an individual Quality Manager who has designated responsibility and authority to ensure the effective operation of the Quality Management System. A complete list of the main duties and responsibilities for the Quality Manager (**SG-EXT-G022** Quality Training and POCT Manager Job Description) can be found on Q-Pulse.

The Quality Manager has delegated responsibility and authority to:

* Ensure that processes needed for the Quality Management System are established, implemented, maintained and improved
* 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.
* Ensure effectiveness of laboratory activities
* Ensure risk management is applied to all laboratory processes

# 5.5 Objectives and policies

## Quality Policy

The Quality policy is held as controlled document within Q-Pulse (**SG-MPOL-035** – Quality Policy). Copies are displayed on departmental notice boards on Level 1 of the Laboratory Medicine and FM building, and Level 2 Laboratory at the Victoria Ambulatory Care hospital (VACH). The quality policy is reviewed at the annual management review (AMR) meeting as per **SG-MPOL-006** Annual Management Review Policy.

## Quality Objectives and Plans

The quality objectives (**SG-MPOL-041** – Quality Objectives) for the Directorate are discussed, agreed and documented at the AMR meeting between the senior management team in Haematology and the Clinical Lead and Senior Diagnostics Directorate staff. Objectives and plans are further reviewed quarterly at the Senior Staff meeting (SSM) to whether the objectives have been successfully progressed and provides opportunity for revising these objectives if required. The Laboratory Management Team defines the quality objectives and plans of the laboratory and is responsible for ensuring that plans are made to meet these objectives.

The department has established a Quality Management System (QMS) that consists of:

* Quality manual (**SG-MPOL-001**)
* Quality policy (**SG-MPOL-035**)
* Quality plans and objectives (**SG-MPOL-041**)
* Quality Management System (Q-Pulse)

Policies, procedures and all other required documentation is controlled, reviewed and distributed via the laboratories QMS system Q-Pulse. The QMS is subject to continual review by planned and scheduled internal audits, and external audit, in accordance with **SG-MPOL-025** Policy and Procedure for Departmental Audits.

# Quality Manual

The department’s Quality Manual is designed to satisfy the requirements of the ISO15189:2022 standards for Medical Laboratories and contains:

* The quality Policy (SG-MPOL-035) see appendix 2
* The scope of the quality management system
* The organisational and management structure of the laboratory and its place in any parent organisation
* The roles and responsibilities of laboratory management
* The structure and relationships of documents within the QMS
* The managerial and technical activities that support the QMS

The Quality Manual is documented, reviewed and distributed within Q-Pulse, and included as key document as part of staff induction (**SG-TRAIN-009** Priority Q-Pulse documents for Induction) All staff have access to the Quality Manual and a copy is available for patients and user on the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/).

# Quality Indicators

Quality Indicators are established and monitored as per **SG-MPOL-040** - Quality Indicators and are broken down into pre-examination, examination, and post-examination phases as a framework for the internal audit program, assessment of service Quality and Improvement, and the setting of Quality Objectives and Plans. These audits are recorded in the Q-Pulse audit module. The documents (**SG-MPOL-024**), (**SG-MPOL-045**) and (**SG-MPOL-025**), contain the details of the processes to be found and how findings are reported. Quality indicators are reviewed at monthly Quality Management meetings as per **SG-MREC-100** quality management meeting agenda.

# 5.6 Risk Management (ISO 5.6 a-b)

The department’s risk management objectives are to manage risks to service quality and to manage the safety of patients, visitors in staff in accordance with ISO15189:2022 and the Blood Safety and Quality regulations (BSQR), 2005. The department achieves this objective by operating in accordance with **SG-MPOL-044** Risk Management Policy and **SG-MPOL-052** Clinical Risk Management to identify and manage risk and opportunities for improvement within the laboratory (see also 8.5 actions to address risks and opportunities for improvement)

The Laboratory director responsibility/delegation of risk management is described in **SG-MPOL-007** Personnel Management and 5.2 Laboratory Director.

# 6. Resource Requirements (ISO 6.1 – 6.8)

# 6.1 General

Laboratory Management is committed to ensuring resources are available to manage and perform its activities. This includes ensuring the availability of suitably trained staff, adequate facilities, equipment, reagents and consumables.

# 6.2 Personnel (ISO 6.2.1 – 6.2.5)

## 6.2.1 General (ISO 6.2.1 a-d)

The department follows NHS Greater Glasgow and Clyde personnel management policies and procedures for staff recruitment and selection, grievance procedures and staff disciplinary action. These policies may be found on Q-Pulse as well as StaffNet. The department has a personnel policy that summarises the most relevant points in these policies (**SG-MPOL-007**).

Personnel records and job descriptions are located in the personnel files of each staff member, and on the Q-Pulse People Module.

The department ensures all staff are trained, competent and authorised to perform laboratory tasks and activities in accordance with **SG-MPOL-008** Training Policy; please refer to this document for full details including the departmental training plan.

Departmental induction and orientation is performed in accordance with **SG-MPOL-010** Induction Policy and recorded on **SG-FORM-G017** Induction checklist, and **SG-FORM-G087** Induction Checklist for Medical Staff. All grades of staff who work in Blood Transfusion shall complete the relevant GMP and other associated Blood Transfusion modules on Learn Pro. Key QMS documents (**SG-TRAIN-009**) are distributed as part of induction including the Quality Manual (**SG-MPOL-001**), Quality Policy (**SG-MPOL-035**) and User Handbook (**SG-MPOL-039**), along with **SG-TRAIN-G026** Introduction to Quality and Root Cause Analysis presentation, is delivered to new staff to communicate the importance of meeting the needs and requirements of users, and meeting the requirements of ISO15189:2022 standards and BSQR, 2005 legislation.

## 6.2.2 Competence requirements (ISO 6.2.2a-d)

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

Training and Education is delivered in accordance with the policies of NHSGGC, guidelines from relevant professional and registration bodies and **SG-MPOL-008** Training policy

The department performs competency assessments, and training and competency programmes are in place as per **SG-MPOL-008** Training policy. The standard training and competency records can be found in Q Pulse (SG-CA-XXXX)

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

They include:

* Principles of the test
* Clinical relevance of the test
* Specimen Reception
* Procedures and instructions
* Storage and retention
* Equipment and supplies
* IQC and EQA
* Recording and reporting results

## 6.2.3 Authorisation (ISO 6.2.3a-c)

The department’s policy is that staff may only perform specific tasks/procedures once they have been authorised to. This authorisation is given in the form of a completed and signed competency and training assessment as per **SG-MPOL-008** Training Policy.

Details of what grade of staff authorised to perform a specific procedure can be found in the staffing requirements section of the specific SOPs for each area (SG-SOP-XXXX), this will be updated as part of the document review cycle.

## 6.2.4 Continuing education and professional development

Continuing Professional development (CPD) is encouraged and facilitated by the department as per **SG-MPOL-007** Personnel Management and **SG-MPOL-008** Training Policy. All staff are given the opportunity for further education and training, in relation to the needs of the service, and their professional development. Additionally there is a requirement from the registration body (HCPC) that registrants must maintain CPD.

Staff have access to continuing education and training, including, online resources such as LearnPro, in-house training and appropriate training and competency programmes.

Staff shall participate in and record (CPD); although membership of a particular scheme is not required, and are encouraged to record their CPD on Q-Pulse.

## 6.2.5 Personnel records (ISO 6.2.5a-e)

The department holds records of the relevant educational and professional qualifications, training, experience and assessments of each staff member in accordance with **SG-MPOL-004** Policy & Procedures for the Control of Process and Quality Records

Staff records held include:

* Personal details
* Employment details
* Job description
* Terms and conditions of employment
* Educational and Professional qualifications
* Staff induction
* Attendance at Mandatory courses
* Training and competency records
* HCPC registration status
* Joint annual review records
* Absence record
* Record of disciplinary action
* Correspondence
* Contract of Employment

These records are held on several different systems. Staff occupational health records are held within the Occupational Health Department.

# 6.3 Facilities and environmental conditions (ISO 6.3.1 - 6.3.5)

## 6.3.1 General

The department provides routine and specialised services from 3 laboratories situated at:

* QEUH
* RCH
* VACH

RCH laboratory provides FBC testing for Paediatric Haemato-Oncology day-care ward and clinics only from 08:45-17:00 hrs Monday- Friday.

VACH operates a limited repertoire of haematology tests from 08:45-17:00hrs Monday-Friday only.

QEUH, RCH and VACH are modern, purpose-built facilities designed to ensure the quality, reliability and efficacy of the service, and to ensure the health and safety of our patients, visors and staff.

## 6.3.2 Facility controls (ISO 6.3.2 a-e)

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. **SG-EXT-G019** NHSGGC Confidentiality and data protection policy applies to all staff employed by NHSGGC. It is also relevant to contractors, partnership organizations and visitors not employed by NHSGGC but engaged to work with, or who have access to health board information.

Visitors to the Laboratory must be accompanied by Laboratory Staff at all times; staff and visitors must abide by **SG-MPOL-020** Policy and Procedures for Staff and Visitors, and **SG-WI-G010** Model Rules for Visitors to Laboratories.

The laboratories are maintained to provide a functional and safe work environment. All work areas are kept clean and well maintained. The department has put measures in place throughout its processes and procedures to minimise the risk of cross-contamination; individual examination SOPs (**SG-SOP-XXXX**) detail regular maintenance and decontamination methods, and all staff must adhere to and work in accordance with **SG-MPOL-009** health and safety policy. The health and safety policy is a key QMS document issued to all staff during departmental induction.

The laboratory monitors and records environmental conditions as required by the BSQR and other guidelines, so that these do not invalidate the results or adversely affect the quality of any process. **SG-MPOL-025** audit policy describes equipment maintenance, health and safety, and fire audits which are scheduled via the internal audit schedule and recorded using the Q-Pulse audit module. Out-with the audit schedule, any environmental issues and concerns e.g. temperature issues, are reported to the NHSGGC Estates and Facilities department via the FM First Web Client (FM First icon on desktop screens)

The laboratory monitors and records environmental conditions as required by the BSQR and other guidelines, so that these do not invalidate the results or adversely affect the quality of any process.

## 6.3.3 Storage facilities (ISO 6.3.3 a-c)

Multiple storage facilities exist with the ability to store the supplies required for laboratory processes at in both ambient and temperature controlled conditions (please refer to **SG-MPOL-005** Policy & Procedures for the Control of Clinical Material, and **SG-MPOL-013** Policy and Procedures for the Procurement and Management of Reagents, Calibration and Quality Control Material)

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.

A comprehensive alarm system is in place for cold rooms, and temperature controlled equipment (**SG-SOP-G022** Envigil temperature monitoring). 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.

Disposal of hazardous materials and biological waste is described in **SG-MPOL-009** Health and Safety policy.

## 6.3.4 Personnel facilities

All staff have access to facilities which make provision for personal safety, comfort and hygiene (**SG-MPOL-007** personnel management)

They include:

* Sufficient toilet and washroom facilities
* A Staff Room
* Basic catering facilities and/or catering vendors
* Access to drinking water and/or catering vendors
* Secure lockers for the storage of personal effects
* Storage for protective clothing

At QEUH there are conference/seminar rooms available for meetings and training events.

There are quiet study areas at QEUH with printing and internet facilities as described in **SG-MPOL-008** Training policy.

## 6.3.5 Sample collection facilities (ISO 6.3.5 a – d)

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

Advice on sample types, labelling requirements and other relevant information is available in SG-MPOL-039 User Handbook which is available for users to access via the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

# 6.4 Equipment (ISO 6.4.1 – 6.4.7)

## 6.4.1 General

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

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

All equipment is managed and maintained in accordance with the Management of Laboratory Equipment policy (**SG-MPOL-011**) and reagents and consumables (**SG-MPOL-013**)

Analyser software will be validated as part of validation plan **SG-VAL-G001** Validation plan template. To meet the requirements of the BSQR, 2005 and ISO15189 standards, the LIMS is validated annually and is the responsibility of NHSGGC Laboratory IT team **SG-VAL-B037** LIMS revalidation report.

## 6.4.2 Equipment requirements (ISO 6.4.2 a – d)

Any equipment that could influence laboratory activities is added to the Q-Pulse equipment module along with records of any maintenance activity as described in **SG-MPOL-011** Policy and Procedures for the Procurement and Management of Equipment.

## 6.4.3 Equipment acceptance procedures

The department validates equipment prior to use in compliance with the validation policy (**SG-MPOL-038**) and equipment management policy (**SG-MPOL-011**). All Equipment and processes must undergo detailed qualification prior to use following the change control and verification procedure (**SG-MPOL-038**) and equipment management policy (**SG-MPOL-011**). The results of the acceptance testing are recorded using **SG-VAL-G001** Validation Report Template and stored in Q-Pulse in accordance with **SG-MPOL-004** Policy & Procedures for the Control of Process and Quality Records.

## 6.4.4 Equipment instructions for use (ISO 6.4.4 a – d)

Standard Operational Procedures and Work Instructions are in place; these describe the safe operation, quality assurance and maintenance of equipment. These are based on the relevant manufacturers’ recommendations, manuals and appropriate guidelines and copies of all may be found on Q-Pulse. Manufacturer manuals are also available in hard-copy or in Q-Pulse.

All equipment in the department is used by trained, competent and authorized personnel, or under their supervision if being trained. 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 or hard copies held in individual staff training folders.

## 6.4.5 Equipment maintenance and repair (ISO 6.4.5 a – d)

All equipment has programmes of Preventive Maintenance which at a minimum, follow the manufacturer/supplier’s recommendations. Records of preventive maintenance are kept against the relevant equipment record in the asset module of Q-Pulse in compliance with the equipment management policy (**SG-MPOL-011**).

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

These contracts should be reviewed annually taking into account quality of service provision.

Preventive maintenance is carried out by trained, competent and authorised laboratory staff according to manufacturer’s/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 assessed that there may have been a potential affect then suitable remedial and corrective actions are undertaken. Upon repair of the equipment verification checks are made to ensure that it is performing in an acceptable manner prior to 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, 2005 is maintained.

An **SG-FORM-G022** Permit to workform must be completed prior to an engineer commencing work on any equipment; completed permit to work forms are attached to the individual asset record within the Q-Pulse equipment module.

## 6.4.6 Equipment adverse incident reporting

Adverse incidents associated with the use of equipment are recorded using **SG-FORM-G011** Equipment Fault and Downtime form; equipment adverse incidents are discussed at monthly quality meetings. In addition any equipment failures which have resulted in the release of incorrect results must be logged via the Datix reporting system in accordance with **SG-MPOL-045** Incident Management Policy and Procedure. Any serious equipment failure or trends that indicate equipment issues must be alerted to the equipment supplier and also to the MHRA (for compliance with the BSQR) or HSE if necessary.

## 6.4.7 Equipment records (ISO 6.4.7 a – k)

Records for all equipment located within the department are kept on the Equipment Module of Q-Pulse, supplier details are within the suppliers’ module. Manuals and other suppliers’ documentation are assigned a unique identifier and version number in Q-Pulse in accordance with **SG-MPOL-003** Document control policy, however, 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 and retained for time period specified in **SG-MPOL-004** Policy & Procedures for the Control of Process and Quality Records. Full details of this process are described within management policies (**SG-MPOL-011, SG-MPOL-005, and SG-MPOL-038**)

As a minimum, equipment records detail the following:

* The Identity of the equipment.
* The manufacturer’s name,
* The model
* The serial number.
* A unique equipment number.
* Contact information for the equipment supplier.
* Date of receipt into the laboratory (if known).
* The date the equipment entered into use (if known).
* The location of the equipment.
* Equipment condition when received
	+ New
	+ Used
	+ Reconditioned.
* Manufacturer’s instructions
* Records that confirm the equipment’s initial acceptability for use.
* Unscheduled Maintenance records.
* Preventative maintenance records.
* 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, 2005 is maintained.

# 6.5 Equipment calibration and metrological traceability (ISO 6.5.1 – 6.5.3)

## 6.5.1 General

All equipment is calibrated on a planned basis by competent personnel. This may be performed by trained, competent and authorised laboratory staff however will most likely be performed 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.
* 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 shall be provided for the test equipment used to carry out calibration to indicate metrological traceability and a copy will be retained for reference and uploaded to the appropriate record in Q-Pulse in accordance with **SG-MPOL-037** Policy and Procedure for Calibration, Metrological Traceability and Measurement of Uncertainty.

Where these calibrations are for equipment relating to blood, blood products or processes related to the Blood transfusion service compliance with the BSQR, 2005 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.

## 6.5.2 Equipment calibration (ISO 6.5.2 a – f)

The requirements for equipment calibration are detailed for the department in **SG-MPOL-037** Policy and Procedure for Calibration, Metrological Traceability and Measurement of Uncertainty and specific Calibration requirements are stated in individual examination procedures (**SG-SOP-XXXX**).

## 6.5.3 Metrological traceability of measurement results (ISO 6.5.3 a – e)

The department ensures metrological traceability of measurement results by following the guidance in TPS-41 UKAS Policy of Metrological Traceability (**SG-EXT-G013**) and processes described in **SG-MPOL-037** Policy and Procedure for Calibration, Metrological Traceability and Measurement of Uncertainty. Specific Calibration requirements are stated in individual examination procedures (**SG-SOP-XXXX**).Where these calibrations are for equipment relating to blood, blood products or processes related to the Blood transfusion service compliance with the BSQR, 2005 is maintained.

# 6.6 Reagents and consumables (ISO 6.6.1 – 6.6.7)

## 6.6.1 General

The processes for the procurement and management of reagents and consumables is described in **SG-MPOL-013** - Policy and Procedures for the Procurement and Management of Reagents, Calibration, Quality Control Material and Consumables. These procedures include:

* Assessment of suitability of materials (acceptance testing).
* Receipt of goods.
* Safe storage and issue of records.
* Safe disposal.

## 6.6.2 Reagents and consumables – Receipt and storage

Reagents and consumables are received and stored in accordance with processes described in **SG-MPOL-013** Policy and Procedures for the Procurement and Management of Reagents, Calibration, Quality Control Material and Consumables. Further detail is also provided in individual SOPs for haematology, haemostasis and blood transfusion sections of the laboratory in the following documents:

* **SG-SOP-B047** - Batch acceptance in blood bank
* **SG-SOP-H037**- Batch acceptance in haematology
* **SG-SOP-C021**- Batch acceptance in Coagulation

## 6.6.3 Reagents and consumables – Acceptance testing

All reagents and kits must be verified before first use or release of patient results, and all consumables that can affect the quality of examinations shall undergo batch acceptance before first use. The policy and procedures for acceptance testing is described with the following documents:

* **SG-MPOL-013** Policy and Procedures for the Procurement and Management of Reagents, Calibration, Quality Control Material and Consumables
* **SG-SOP-B047** - Batch acceptance in blood bank
* **SG-SOP-H037**- Batch acceptance in haematology
* **SG-SOP-C021**- Batch acceptance in Coagulation

## 6.6.4 Reagents and consumables – Inventory Management

The department uses Reagent Management System (RMS) for inventory management as per **SG-SOP-G018** - Reagent Management System. Details relating to the stock management of reagents, calibration, quality control materials and consumables, are defined within individual section procedures:

* **SG-SOP-B047** - Batch acceptance in blood bank
* **SG-SOP-H037**- Batch acceptance in haematology
* **SG-SOP-C021**- Batch acceptance in Coagulation

## 6.6.5 Reagents and consumables – Instructions for use

Instructions for use are readily available for all reagents; these can be found in the individual SOPs or manufacturer’s package inserts. Instructions for use are held in folders within the laboratory and in the Q-Pulse document module.

## 6.6.6 Reagents and consumables – Adverse incident reporting

Any supplier issues, field safety notices (FSN), product recalls are recorded within the Q-Pulse non-conformance module in accordance with **SG-MPOL-045** Incident Management policy. Suppliers and incident reviews are discussed at monthly quality meetings as a standing agenda item (**SG-MREC-100 Quality** group agenda) and at the annual management review (AMR). Additionally, a pan GGC MSC Steering group meets on a monthly basis to discuss performance of the suppliers who provide those services (**SG-MREC-068**).

## 6.6.7 Reagents and consumables – Records

The department maintains records of reagents and consumables in accordance with **SG-MPOL-013** Policy and Procedures for the Procurement and Management of Reagents, Calibration, Quality Control Material and Consumables and **SG-MPOL-004** - Policy & Procedures for the Control of Process and Quality Records.

# 6.7 Service agreements (ISO 6.7.1 – 6.7.2)

## 6.7.1 Agreements with laboratory users (ISO 6.7.1 a – c)

The procedure for establishing service agreements is described within **SG-MPOL-022** Policy and Procedure for the Management of a Service Level Agreement. The requirement to define service user requirement, including where appropriate formal contracts is identified by the department as an essential prerequisite of a quality service.

Service Level Agreement (SLA) is considered as part of the negotiation of a service contract agreed between the department and the user andwhere the level of service is formally defined.

The Department acknowledges that:

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

## 6.7.2 Agreements with POCT operators

This is not applicable to NHSGGC Haematology and Blood Transfusion, South sector; POCT is not managed by the laboratory.

# 6.8 Externally provided products and services (ISO 6.8.1 – 6.8.3)

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 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 in use. The policies and procedures for use of this system are outlined within the Standing Financial Instructions.

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, please refer to **SG-MPOL-031** Verification & Selection of MSC Third Party

The Department:

* Selects and approves suppliers based on their ability to supply services, equipment, reagents and consumables in accordance with contracted requirements.
* 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.
* Monitors the performance of suppliers to ensure that purchased services or items consistently meet accepted criteria.

The Departmental Referral Policy (**SG-MPOL-015**) contains the general information on sample referral. The Section Specific Procedure Documents (**SG-SOP-G005** and **SG-SOP-B016**) contains the procedures for the 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:

* Evaluation and selection of referral laboratories to perform referred examinations.
* A list of testing laboratories that samples are referred to (also available in **SG-MPOL-039** - User handbook)
* Records of referrals include dates of dispatch, the transport route, 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
* Arrangements with referral Laboratories are formally reviewed to ensure that requirements including terms of EQA performance and turnaround times are satisfactory to requirements.

The procedure documents (**SG-SOP-G005-** Referring sample to another Laboratory), and (**SG-SOP-B016 -** SNBTS sample referral) contains the general requirements for referral sample result reporting including.

* Identification of referral laboratory or Consultant.
* Transcription and reporting of Results and interpretative comments.
* The addition of any further comments.

The performance of referral laboratories and suppliers is monitored by quarterly and annual audits, respectively, in accordance with **SG-MPOL-025** Policy and Procedure for Departmental Audits to check for any changes relating to accreditation status, sanctions and contact details; the Q-Pulse supplier record is then updated as required.

The performance of suppliers including associated incidents are reviewed and discussed at monthly quality meetings as a standing agenda item (**SG-MREC-100** Qualitygroup agenda) and at the AMR.

# 7. Process Requirements (ISO 7.1 – 7.8)

## 7.1 General

The Laboratory has implemented **SG-MPOL-052**- Clinical Risk Management to identify potential risks to patient care throughout examination processes. These risks are monitored and evaluated in relation to the potential for patient harm.

The Laboratory is committed to continual improvement of the services provided and details of how we aim to achieve this are described in **SG-MPOL-024** - Procedure for the management of Evaluation & Continual Improvement

## 7.2 Pre-examination processes

7.2.1 General

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

## 7.2.2 Laboratory information for patients and users (ISO 7.2.2 a – g)

**SG-MPOL-039** - User Handbook provides information to services users and patients and is available on the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

This includes:

* The location of the laboratory;
* The types of services offered by the laboratory
* Examinations referred to other laboratories;
* Opening hours of the laboratory;
* The examinations offered by the laboratory
* Information on samples
	+ Type required
	+ Primary sample volumes
	+ Special precautions,
* Turnaround times
* Biological reference intervals
* Instructions for completion of a manual request form.
* Transportation of samples
* 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 availability of clinical advice on ordering of and interpretation of examinations and results
* The laboratory’s policy on data confidentiality.

Please note that ISO15189:2022 7.2.2e) requirements for patient consent is out with the scope of this laboratory; samples are taken by venepuncture which infers consent. For specialist samples/tests such as bone marrow aspirates, CSF samples, haemoglobinopathy testing, consent would be the responsibility of the requesting clinician. Consent to blood transfusion is also out with the scope of this laboratory, however, information is available for users and patients via the Transfusion policy on SharePoint [GGC Blood Transfusion information - Home (sharepoint.com)](https://scottish.sharepoint.com/sites/GGCBloodTransfusioninformation2)

## 7.2.3 Requests for providing laboratory examinations (ISO 7.2.3.1 – 7.2.3.2)

As defined in service agreement procedures (please see 6.7.1); each request accepted by the laboratory for an examination procedure will be considered an agreement.

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 (**SG-MPOL-039),** a copy of the handbook is available for users and patients on the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

**SG-SOP-G012** Haematology Specimen Reception updated with regards to receipt of telephone add-on requests and cross-reference relevant work instructions. **SG-SOP-B025** Blood Bank reception described dealing with urgent telephone requests; no update required.

Handwritten and Trakcare request forms are accepted, and GP ICE labels are accepted without a request form as stated in **SG-MPOL-039** – user handbookand **SG-SOP-G012-** Haematology Specimen Reception. The manual request form and electronic requesting includes the following items:

* Unique identification of the patient.
	+ Full name
	+ Hospital Case Reference Number (CRN)/Community Health Index (CHI) number
	+ Date of birth
* identification and the location of the requestor
* Date and time of specimen collection
* The type of specimen
* The investigations requested
* Date and time of specimen receipt by the laboratory
	+ Recorded on LIMS
	+ Time Stamped
* Relevant clinical information
* identification of priority status
* Laboratory number

**SG-SOP-B025** Blood Bank reception describes sample and request form acceptance procedures specifically for blood transfusion samples.

Procedures for add-on tests are described in **SG-MPOL-039** – user handbookand **SG-SOP-G012 -**Haematology Specimen Reception; please see also section 7. Patient/specimen requirements in individual examination procedures (**SG-SOP-XXXX**)

## 7.2.4 Primary sample collection and handling (ISO 7.2.4.1 – 7.2.4.4)

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, including Phlebotomy Staff. Laboratory staff do not participate in sample collection or transportation.

Information for service users for sample collection activities, including the completion of the request (manual or electronic), sample type and volume required is provided in the service user handbook for the department of haematology (**SG-MPOL-039**); **SG-SOP-G012** Haematology Specimen Reception and **SG-SOP-B025** Blood Bank reception also describe processes for sample collection. Information is also displayed on the Trakcare system.

Rejected samples are audited monthly in accordance with **SG-MPOL-025** Policy and Procedure for Departmental Audits, and findings are reviewed and discussed at monthly quality meetings as a standing agenda item (**SG-MREC-100)**

**SG-MPOL-005** Policy & Procedures for the Control of Clinical Material section 2 consent describes the use of patient samples for audit and IQC purposes. As the majority of our samples are venepuncture, in accordance with ISO15189:2022 7.2.4.3, consent is therefore inferred. Specific consent maybe required for Bone Marrow aspirate or Haemoglobinopathy samples, however this is out with the control of the laboratory and responsibility for obtaining consent lies with the clinician.

## 7.2.5 Sample transportation (ISO 7.2.5 a – c)

**SG-MPOL-039** user handbook provides information for sample transport; this can also be accessed by patients and users on the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

There is an established NHSGGC policy for the transportation of specimens by porters and couriers (**SG-EXT-G028** NHS GGC Policy for Safe Transport and Disposal of Samples) in compliance with regulatory requirements and includes:

* Ensuring 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
	+ The safety of personnel

Transportation of samples is governed by **SG-MPOL-019** - Policy for Specimen Transport of samples across GGC Sites, which describes processes to transport and receive biological specimens in a legally compliant and safe manner.

To ensure suitability of transportation systems is reviewed, quarterly sample transport audits are performed in collaboration with combined specimen reception as per **SG-MPOL-025** audit policy to review TAT from sample receipt to reporting of sample deliveries over one full day; audits are recorded within Q-Pulse audit module.

## 7.2.6 Sample receipt (ISO 7.2.6.1 – 7.2.6.2)

The overarching policy for sample reception is described in **SG-MPOL-014** - Policy and Procedure for Specimen Reception. The department follows a separate documented procedure for the discipline specific specimen receptions located within the laboratory:

* **SG-SOP-G012** - Haematology Specimen Reception (for paediatric and adult Haematology)
* **SG-SOP-B025** - Blood Bank Specimen Reception (for blood transfusion)

Each of these documents provide instructions for:

* Accurate identification of the request and specimen
* Registration of the request form and specimen information into the laboratory computer
* Handling urgent specimens
* Specimen rejection processes

## 7.2.7 Pre-examination handling, preparation and storage (ISO 7.2.7.1 – 7.2.7.3)

The department has established procedures and appropriate facilities for the secure storage of patient samples and ensuring sample integrity is maintained. These are described in:

* **SG-MPOL-039** user handbook
* **SG-MPOL-005** storage of clinical material

The department uses the Envigil system for electronic temperature monitoring across all South Sector Haematology laboratory sites (QEUH, RHC and VACH)**.** The Envigil system monitors all the critical storage facilities in Transfusion, Haematology and Coagulation and the satellite blood fridges as described in **SG-SOP- G022** Envigil System – Electronic Temperature Monitoring.

# 7.3 Examination processes

## 7.3.1 General (ISO 7.3.1 a – e)

**SG-MPOL-028** Change Control Policy and Procedure, **SG-MPOL-016** - Policy and Procedure for selection and validation of examination procedures, **SG-MPOL-029** - Validation Master Plan for Blood Transfusion Equipment**SG-MPOL-038** - Policy and Procedure for the Validation of Equipment and associated documents describe the procedures and requirements for Change Control and the evaluation and performance of validation and verification of examination methods. All data is uploaded to Q-Pulse.

Examination methods are defined (**SG-SOP-TEMP** – SOP template) using guidance document **SG-SOP-G010** - Instructions on how to complete SOP template **SG-MPOL-003** Document Control Policy ensures all documentation is reviewed and distributed via Q-Pulse.

Personnel can perform examinations for which they have been trained and assessed as competent (**SG-MPOL-008** Training policy and **SG-MPOL-007** Personnel Management) and the LIMS records the identity of staff performing significant activities as per **SG-SOP-G016** – Telepath.

The suitability of examinations is reviewed as a standing agenda item at the quarterly Senior Staff Meeting (SSM) (**SG-MREC-096**) and Annual Management review (AMR) (**SG-MREC-106**)

## 7.3.2 Verification of examination methods (ISO 7.3.2 a – f)

**SG-MPOL-028 Change Control Policy and Procedure, SG-MPOL-016** - Policy and Procedure for selection and validation of examination procedures, **SG-MPOL-038** - Policy and Procedure for the Validation of Equipment and associated documents describe the procedures and requirements for Change Control, evaluation and performance of the verification of processes.

This includes:

* Specimen requirements
* Equipment and supplies
* Reagents, standard(s) and/or calibrants
* IQC
* EQA
* Calibration
* Instructions for use
* Limitations.
* Interferences.
* Cross reactions.
* Reportable intervals of the examination.
* Recording and calculation of results (if appropriate).
* Reference limits.
* Hazards and safety precautions (risk assessment).
* Performance criteria
* Uncertainty of Measurement estimation.

Staff authorised to conduct performance testing and review the results are defined within **SG-MPOL-016, SG-MPOL-029** and **SG-MPOL-038**.

In accordance with **SG-MPOL-045** – Incident Management policy, upon receipt of a Field Safety Notice (FSN) from a supplier, the impact of the FSN must be assessed as soon as possible by a Senior BMS and/or Laboratory Manager. Corrective action may include re-verification of the examination method and review of associated examination process clinical risk assessments (individual clinical risk assessments held within Q-Pulse document module **SG-RA-XXXX**)

Change control records, verification reports and associated data are held within the document module of Q-Pulse in accordance with **SG-MPOL-004** Policy & Procedures for the Control of Process and Quality Records

## 7.3.3 Validation of examination methods (ISO 7.3.3 a – e)

**SG-MPOL-028** Change Control Policy and Procedure**, SG-MPOL-016** - Policy and Procedure for selection and validation of examination procedures, **SG-MPOL-038** - Policy and Procedure for the Validation of Equipment and associated documents describe the procedures and requirements for Change Control, evaluation and performance of the validation of processes.

Staff authorised to conduct performance testing and review the validation results are defined within **SG-MPOL-016, SG-MPOL-029** and **SG-MPOL-038**.

Validation reports and associated data are held within Q-Pulse in accordance with **SG-MPOL-004** Policy & Procedures for the Control of Process and Quality Records

## 7.3.4 Evaluation of measurement of uncertainty (MU) (ISO 7.3.4 a – h)

**SG-MPOL-037** Policy and procedure for calibration, metrological traceability and measurement uncertainty and describes how Measurement Uncertainty (MU) is managed in pre-exam, exam and post-exam phases within the laboratory. MU for test results is calculated annually and recorded using **SG-FORM-G026** - Calculated Measurement of Uncertainty Values, and held within Q-Pulse. MU for test results are made available to service users via **SG-MPOL-039** user handbook. MU is also defined in section 16. Limitations, within individual examination SOPs (**SG-SOP-XXXX**).

## 7.3.5 Biological reference intervals and clinical decision limits (ISO 7.3.5 a – d)

These are included in the individual examination procedures and in the service user handbook for the department of haematology (**SG-MPOL-039**) to be available to service users via the [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

Periodic review of reference ranges is discussed under ‘review of laboratory examination procedures’ which is a standing agenda item at the quarterly Senior Staff Meeting (SSM) (**SG-MREC-096** - QEUH Senior Staff Meeting Agenda**).** Review of reference ranges may also be discussed at haematology management meetings (HMT) if required.

## 7.3.6 Documentation of examination procedures (ISO 7.3.6 a – f)

**SG-SOP-TEMP -** SOP Template is used to record all examination procedures, and ensure consistent application of activities and validity of results.

All documents are managed and controlled via the QMS system Q-Pulse; documents are controlled and reviewed biennially or sooner as stated in **SG-MPOL-003** document control policy.

Requirement for communication of change in examination procedures to users is assessed as part of **SG-CC-G001** - Change control form.

# 7.3.7 Ensuring the validity of examination results (ISO 7.3.7.1 – 7.3.7.4)

## 7.3.7.1 General

**SG-MPOL-023** – Policy and Procedure for Quality Assurance outlines the department’s procedures for quality assurance ensuring validity of results, trending and monitoring of results and statistical analysis. Results are reviewed at monthly quality management and technical senior staff meetings, and as part of the annual management review as defined in **SG-MPOL-023.**

## 7.3.7.2 Internal quality control (IQC) (ISO 7.3.7.2 a – g)

**SG-MPOL-023** – Policy and Procedure for Quality Assurance defines the departmental internal quality control procedure including:

* Use of multi-level controls pertinent to clinical decision making
* Frequency of IQC for each examination
* Defined IQC acceptance and rejection criteria for each examination
* Scheduled review of IQC performance
* Use of third party control material

QEUH Haematology Justification spreadsheet (**SG-MPOL-023** – Policy and procedure for Quality Assurance) details test type, stability, multi-level QC details, frequency, suitability, comparability and preventive measures in the event of IQC failure for each examination.

Frequency of IQC is also considered within clinical risk assessments for individual examination processes (**SG-RA-G028** –Clinical Risk Assessment template)

Action required in the event of IQC failure is defined within **SG-MPOL-023** – Policy and procedure for quality assurance, and the quality control section of individual examination procedures. Continual performance of Sysmex XN analysers for FBC processing using drift QC and X-BarM is further defined within **SG-SOP-H011**- Processing Full Blood Counts on Sysmex XN and TS10 tube sorter.

Review of IQC providers and performance is discussed as a standing agenda item at monthly at Quality Management Meetings (**SG-MREC-100** - QEUH Haem/BT Quality Group Agenda)

## 7.3.7.3 External quality assessment (EQA) ISO 7.3.7.3 a – i)

**SG-MPOL-023 -** Policy and Procedure for Quality Assurance defines procedures for external quality assessment including:

* Enrolment, participation and performance
* Staff authorised to process EQA samples
* Suitability and selection of EQA providers compliant with ISO 17043 requirements
* Alternate approaches to EQA in the absence of a suitable EQA scheme

**QEUH Haematology EQA Justification** spreadsheet (**SG-MPOL-023** – policy and procedure for Quality Assurance) describes the type, frequency and justification of EQA material the laboratory requires to adequately perform EQA analysis.

Review of EQA performance is recorded on EQA review forms **SG-FORM-B002, SG-FORM-C002** to **–C003** and **SG-FORM-H003** to **– H015)** which are held in the laboratory. All EQA reports are discussed as a standing agenda item at the monthly Quality Management Meetings (**SG-MREC-100** - QEUH Haem/BT Quality Group Agenda) and the Annual Management Review (**SG-MPOL-006** – Annual Management Review Policy).

Where EQA results are found to be out with consensus or persistent poor performance (PPP), appropriate action including assessment of clinical impact is manged as per **SG-MPOL-023** – Policy and Procedure for Quality Assurance, **SG-MPOL-045** - Incident management policy and procedure and **SG-MPOL-052**- Clinical Risk Management. EQA failure is also considered within clinical risk assessments for individual examination processes (**SG-RA-G028** – Clinical Risk Assessment template).

## 7.3.7.4 Comparability of examination results (ISO 7.3.7.4 a – e)

Cross site analysis is performed for those tests performed on more than one site as detailed in **SG-SOP-G011** Comparability procedures for examination results and **SG-MPOL-023** Quality Assurance Policy. This is discussed at the quality meeting and used in the annual review of processes. The data obtained is available on Q-Pulse.

# 7.4 Post-examination processes

## 7.4.1 Reporting of results (ISO 7.4.1.1 a – c)

The department has a policy and procedure for the reporting of results that includes communication guidance on delayed report procedure (**SG-MPOL-043** - Reporting of Results). Reports are available to all NHSGGC users electronically and to others as a printed copy. All documentation associated with reports are stored as described in **SG-MPOL-004** - Policy & Procedures for the Control of Process and Quality Records.

Procedures for reporting results is further described in individual examination procedures in section 17. “Reporting Results (Including responsibilities of personnel & alert/critical values)” (**SG-SOP-TEMP** – SOP template)

## 7.4.1.2 Result review and release

For the department, examination results are reviewed and authorised by trained, qualified, competent and authorised Biomedical Scientist Staff and also, by trained Haematology Medical Staff. Results are reviewed against internal quality control, available clinical information and previous examination results as appropriate. **SG-MPOL-023** Policy and Procedure for Quality Assurance, Table 2. QEUH Haematology IQC Justification, describes the preventive measures in place to prevent the release of patient results in the event of IQC failure (please see 7.3.7.2)

Reporting procedures, including staff authorised to review and release results are described in **SG-MPOL-043** Reporting results. This procedure includes consideration of the following:

* Indication in the report if the quality of the primary sample received was unsuitable for examination.
* Indication in the report if the quality of the primary sample received could have compromised the quality of the result generated.
* Checks to ensure that results are without errors in transcription.
* If an examination result falls within established critical values:
	+ That a clinician or other authorised health professional has been immediately notified.
* If a result has been communicated verbally:
	+ 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
	+ Date and Time of communication
* That checks are made to ensure that results are only made available only to those authorised to receive them.

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

**SG-SOP-G008** - Procedure for making and receiving telephone calls (including results).

Reporting of results is further described within section 5 and section 17 of individual examination procedures (**SG-SOP-TEMP**).

## 7.4.1.3 Critical result reports (ISO 7.4.1.3 a – c)

**SG-MPOL-043** - Reporting results and **SG-SOP-G008** - Procedure for making and receiving telephone calls (including results) detail procedures for reporting critical results including escalation process which for this department, is via the Haematology Medical staff.

Telephone procedures related to critical result transmission are defined in **SOP-G008** Procedure for making and receiving telephone calls (including results).

Procedures for reporting critical results is further described in individual examination procedures in section 17. “Reporting Results (Including responsibilities of personnel & alert/critical values)” (**SG-SOP-TEMP** – SOP template)

## 7.4.1.4 Special consideration for results (ISO 7.4.1.4 a – e)

In accordance with **SG-MPOL-043** – reporting of results, where the referral laboratory issues a detailed and lengthy report, a summary may be entered on the LIMS, including the identity of the referral laboratory, as long as the original full report is scanned and entered onto clinical portal. The LIMS report should be identified as a summary report.

Departmental procedures relating to the telephoning of preliminary results and the logging of calls, are described in **SG**-**SOP-G008** - Procedure for making and receiving telephone calls (including results) and **SG-SOP-B028** - Blood Transfusion Telephone SOP.

All results are shared in accordance with **SG-EXT-G019** NHSGGC Confidentiality policy.

## 7.4.1.5 Automated selection, review, release and reporting of results (ISO 7.4.1.5 a – d)

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.

The procedures for auto-authorising and review of results for reporting are described in the following documents:

* **SG-SOP-G016** Departmental IT procedures for Telepath
* **SG-SOP-H032** Sysmex EPU
* **SG-SOP-B075** OrthoConnect (results section)
* **SG-SOP-B077** Processing Group and Screens (Automated)
* **SG-SOP-B009** Crossmatch Procedure (Automated)
* **SG-SOP-B032** Electronic Issue
* **SG-SOP-C015 ACL** TOP Coagulation screen

EPU and Telepath have functionality that ensures an audit trail of users. If rapid suspension of auto-authorisation is required (**SG-MPOL-043** reporting of results) a rule can be applied in Telepath LIMS by LIMS programmer and in EPU by an EPU laboratory administrator.

## 7.4.1.6 Requirements for reports (ISO 7.4.1.6 a – m)

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.
* Requester
* Location of request
* Type of specimen
* Date and time of collection
* Time and date of report
* Results
* Comment for the reason if no examination is performed
* Reference intervals (age and gender specific where appropriate)
* Interpretive comments (where appropriate)
* Explanatory or cautionary comments about results (where appropriate)
* Highlighting of abnormal results
* Where possible the identification of person(s) verifying the results and authorising the release of the report.

## 7.4.1.7 Additional information for reports (ISO 7.4.1.7 a – d)

The department’s reports communicate the laboratory results and include the following information where required (please see **SG-MPOL-043** reporting results for full details):

* Comments on sample quality that might compromise results.
* Comments regarding sample suitability
* Critical results
* Interpretive comments on results

The department, as defined in **SG-MPOL-049** - GGC South Sector Policy on the Use of, and Reference to: UKAS Accreditation, Symbols and Logos, has chosen not to use UKAS Accreditation Symbols on any paper reports or associated documentation.

The following statement is applied to all test reports generated by the laboratory:

‘**South Haematology Labs are an ISO: 15189 accredited laboratory (UKAS) for scope on schedule. Please see the user handbook for clarification’**

The user handbook, along with a hyperlink directing service users to the UKAS website can be found on the [Haematology and Blood Transfusion - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/) website.

## 7.4.1.8 Amendments to reported results (ISO 7.4.1.8 a – e)

The department operates a systematic process for the amendment of issued or electronically authorised laboratory reports. This process serves to ensure that information regarding amended laboratory reports, either in paper report format, or in electronic format, are conveyed to appropriate Hospital staff. The procedure for the issue of revised/amended reports is described within **SG-SOP-G009** -revised reports which includes:

* The criteria for issuing revised and amended report.
* The identification to the user 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.

# Amended results are archived in the Laboratory Information System (Telepath). Telepath’s AUDIT module shows the amendments to the results including identity of personnel who amended the report.

## 7.4.2 Post-examination handling of samples (ISO 7.4.2 a – e)

The departments stores, retains and disposes of clinical samples in accordance with the requirements of the Human Tissue Act 2004, 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 in accordance with the following documents:

* **SG-MPOL-005** Policy & Procedures for the Control of Clinical Material
* **SG-REF-G024** RCPath Guidelines on the retention and storage of pathological records and archives
* **SG-EXT-G028** NHS GGC Policy for Safe Transport and Disposal of Samples

# 7.5 Nonconforming work (ISO 7.5 a - g)

The department reports clinical and non-clinical incidents, including near misses and potential incidents in accordance with ISO15189 and the BSQR, as described in **SG-MPOL-045** – Incident Management policy and Procedure. Nonconforming work is recorded using the CAPA module on Q-Pulse and DATIX and SHOT/SABRE online reporting systems.

All incidents are investigated and corrective action implemented in accordance with **SG-MPOL-045** (please see 8.7 Nonconformities and corrective actions)

Records of nonconforming work are held in accordance with **SG-MPOL-004** Policy and Procedures for the control of process and quality records.

## 7.6 Control of data and information management (ISO 7.6.1 – 7.6.5)

## 7.6.1 General

The department has a documented procedure **SG-MPOL-012** Policy and Procedure for the Management of IT Systems, Electronic Data and Information, to ensure that the confidentiality of patient information is maintained at all times. The operation of the system is in compliance with data protection legislation, departmental and NHSGGC policies (**SG-MPOL-012** Policy and Procedure for the Management of IT Systems, Electronic Data and Information, **SG-SOP-G016** - Departmental IT procedures for Telepath, **SG-EXT-G019** NHSGGC Confidentiality policy) and the BSQR, 2005.

The system is subject to change control (**SG-MPOL-028** - Change Control Policy and Procedure, verification (**SG-MPOL-038** Policy and Procedure for the Validation of Equipment) and audit (**SG-MPOL-025** - Policy and Procedure for Departmental Audits)

## 7.6.2 Authorities and responsibilities for information management

The authorities and responsibilities of personnel who use the Laboratory Information System (LIMS) are defined in the following documents:

* **SG-SLA-G001** Operational Level Agreement (Telepath) which states the authority and responsibility of NHSGGC eHealth teams.
* **SG-SOP-G016** Departmental IT procedures for Telepath which states user access levels for LIMS use by laboratory personnel

The maintenance and modification of the system are controlled by personnel access levels which restricts those who have the authority and responsibility to perform the following:

* Access patient data and information.
* Entry of patient data and examination results.
* Change patient data or examination results;
* Validate, report and release examination results
* Modify the system

## 7.6.3 Information systems management (ISO 7.6.3 a – e)

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 the following data protection legislation, departmental and NHSGGC policies, and the BSQR, 2005:

* **SG-MPOL-012** Policy and Procedure for the Management of IT Systems
* **SG-SOP-G016** - Departmental IT procedures for Telepath
* **SG-EXT-G019** NHSGGC Confidentiality Policy

The system is subject to change control [SG-MPOL-028] and verification [SG-MPOL-038] and audit.

**SG-VAL-B037** Annual Revalidation LIMS is performed by NHSGGC Laboratories IT team; the report details the control mechanisms in place within NHSGGC that support the operational validation review of NHSGGC Laboratory Information Management System (LIMS). **SG-VAL-B037** Annual Revalidation LIMS report and the annual laboratory software audit are performed in accordance with **SG-MPOL-025 -** Policy and Procedure for Departmental Audits.

The NHSGGC Laboratories eHealth directorate are responsible for implementation of cybersecurity, protecting systems form unauthorised access and safeguarding data. The eHealth SharePoint site provides an overview of the eHealth directorate including links to all information security policies [GGC eHealth - Home (sharepoint.com)](https://scottish.sharepoint.com/sites/GGC-eHealth)

Manual results entry process is documented within individual examination SOPs (**SG-SOP-XXXX)**

## 7.6.4 Downtime plans

Defined action in the event of unscheduled and scheduled downtimes, including the LIMS, is described in **SG-MPOL-034** - business continuity. Details for processing specific samples is described in the following documents:

* **SG-SOP-G013** Processing Haematology and Coagulation Samples in the Event of Computer Failure describes procedures for processing haematology and haemostasis samples during LIMS downtime
* **SG-SOP-B075** Ortho Connect describes procedures for processing Blood Transfusion samples in the event of LIMS downtime

## 7.6.5 Off site management

Off site management of IT systems is covered by NHSGGC eHealth team. Please refer to IT security Policies held within the eHealth SharePoint site [Information Security Policies (sharepoint.com)](https://scottish.sharepoint.com/sites/GGC-eHealth/SitePages/Information-Security-Policies.aspx)

# 7.7 Complaints (ISO 7.7.1 – 7.7.3)

The departmental policy for complaints (**SG-MPOL-026** - Policy and Procedures for Reporting Complaints) and **SG-REF-G027** - NHSGGC Complaints Policy describe how complaints are handled with the aim of satisfying the complainant whilst 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 should contact the NHSGGC Complaints Team by telephone, email or by writing to the NHSGGC Complaints Team. Instructions for users with regards to complaints is provide on the laboratory webpage [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/). If still not satisfied with the response or resolution they then have the opportunity to refer the issue to the Ombudsman.

# 7.8 Continuity and emergency preparedness planning (ISO 7.8 a – d)

Contingency planning procedures are defined in the following documents:

* **SG-MPOL-034** business continuity plan (describes contingency plans for QEUH and VACH for services provided)
* **SG-EXT-G018** GGC Haematology Business Continuity Template (describes the health board’s business continuity management for North, Clyde and South sectors)
* **SG-MPOL-021** Policy in the event of a Major Incident

**8. Management System Requirements (ISO 8.1 – 8.9)**

**8.1 General requirements**

**8.1.1 General**

The department has established a quality management system that consists of:

* Departmental Quality Manual (**SG-MPOL-001**)
* Departmental Quality Policy (**SG-MPOL-035**)
* Departmental Quality Manager
* Departmental Quality Management System (Q-Pulse)

The Department is committed to the development and implementation of the quality management system and continually improve its effectiveness by:

1. Defining responsibilities ([Section 8.1](#_General_requirements_(ISO))
2. Setting objectives and policies ([Section 8.2](#_Management_system_documentation))
3. Documenting information ([Section 8.2](#_Management_system_documentation), [8.3](#_Control_of_management), [8.4](#_Control_of_records))
4. Taking action to address risk and opportunities for improvement ([Section 8.5](#_Action_to_address))
5. Continual improvement ([Section 8.6](#_Improvement_(ISO_8.6)))
6. Implementing corrective actions ([Section 8.7](#_Nonconformities_and_corrective))
7. Performing evaluations and conducting internal audit ([Section 8.8](#_Evaluations))
8. Conducting management reviews ([Section 8.9](#_Management_reviews))

## 8.1.2 Fulfilment of management system requirements

Commitment to fulfilment of management system requirements is described in **SG-MPOL-035** – Quality Policy (Appendix B). This is available to service users via the Departmental website [South Glasgow Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/south-glasgow-sector-haematology/)

## 8.1.3 Management system awareness (ISO 8.1.3 a – c)

Personnel are made aware of the requirement and function of the quality management system via induction proceduresincluding acknowledgment of documents described as follows:

* **SG-MPOL-035** Quality policy defines the department’s commitment to ensuring all staff are familiar with the QMS and relevant procedures.
* **SG-TRAIN-009** Priority Q pulse documents for Induction lists the essential Q-Pulse policy documents that must be issued to all new staff at induction; these are distributed via Q-Pulse for acknowledgement
* **SG-CA-G008** Q-Pulse and Quality Management system competency
* **SG-TRAIN-G026** Introduction to Quality and RCA

Updates to the quality management system are communicated via document control procedures (**SG-MPOL-003** Document control policy) and as follows:

* daily staff huddles
* general staff meetings
* staff newsletters
* AMR

All meeting minutes are made available to staff via Q-Pulse. Local incident meetings are held monthly and any relevant feedback is provided at the staff huddle the following day. Staff are encouraged to contribute to continual improvement of the QMS via **SG-MPOL-047** staff suggestions and by participation in departmental audits as per **SG-MPOL-025** Policy and Procedure for departmental audit.

# 8.2 Management system documentation (ISO 8.2.1 – 8.2.5)

## 8.2.1 General

Management system documentation is defined in **SG-MPOL-001** – Quality Manual.This includes:

1. The quality policy;
2. A description of the scope of the quality management system;
3. A presentation of the organisation and management structure of the laboratory and its place in any parent organisation;
4. A description of the roles and responsibilities of laboratory management (including the Laboratory Director and Quality Manager);
5. A description of the structure and relationships of the documentation used in the QMS;
6. The documented policies established for the quality management system and reference to the managerial and technical activities that support them.
7. All laboratory staff shall have access to and be instructed on the use and application of the Quality Manual and the referenced documents.

## 8.2.2 Competence and quality

The laboratory is committed to addressing the competence, quality and consistent operation of the laboratory as defined within **SG-MPOL-035** Quality Policy.

## 8.2.3 Evidence of commitment

The Laboratory management is committed to the development and implementation of the quality management system and continually improves its effectiveness by:

* Communicating to laboratory personnel the importance of meeting the needs and requirements of users **(SG-MREC-037, SG-MREC-088, SG-MREC-089**)
* Communicating the regulatory and accreditation requirements (**SG-MREC-037, SG-MREC-088, SG-MREC-089** and **SG-MREC-039**)
* Establishing the quality policy (**SG-MPOL-035**)
* Ensuring that quality objectives and plans are established (**SG-MPOL-041**)
* Defining responsibilities, authorities and interrelationships of all personnel (**SG-MPOL-001**)
* Establishing communication processes (**SG-MREC-051, SG-MREC-036**)
* Appointing a quality manager, however named
* Conducting management reviews (**SG-MPOL-006**)
* Ensuring that all personnel are competent to perform their assigned activities (**SG-MPOL-008**)
* Ensuring availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities

## 8.2.4 Documentation

All documentation related to fulfilment of the requirement of BS EN ISO 15189:2022 is controlled and managed in accordance with **SG-MPOL-003** - Document control policy, and can be found within the laboratories QMS system Q-Pulse.

## 8.2.5 Personnel access

All personnel involved in laboratory activities have access to the parts of the QMS applicable to their responsibilities via unique Q-Pulse login (**SG-MPOL-003** document control policy defines Q-Pulse access levels) and access to the departmental shared drive and NHS GGC StaffNet pages.

# 8.3 Control of management system documents (ISO 8.3.1 – 8.3.2)

The policy on document control is contained within document (**SG-MPOL-003**).

Standard document template (**SG-SOP-TEMP**) along with **SOP-SOP-G010** - Instructions on how to complete SOP template ensure that the documents contain:

* A title
* Unique identifier
* Date of current Edition
* Revision number
* Page number to number of pages
* Authority for Issue

QMS documentation is subject to strict control, subject to review and amendment by authorised personnel when appropriate:

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

# 8.4 Control of records (ISO 8.4.1 – 8.4.3)

The Department utilises a procedure for the identification, collection, indexing, access, storage, maintenance, amendment, retention and safe disposal of quality and technical records to ensure that records are created concurrently with performance of each activity that affects the quality of the examination. The procedures are defined in the following documents:

* **SG-MPOL-003** Document control policy
* **SG-MPOL-004** Policy & Procedures for the Control of Process and Quality Records
* **SG-MPOL-012** Policy and Procedure for the Management of IT Systems, Electronic Data and Information
* **SG-REF-G024** RCPath Guidelines on the retention and storage of pathological records

Telepath records all user transactions to ensure that there is a full audit trail of persons performing significant activities in examination procedures (**SG-SOP-G016** Departmental IT procedures for Telepath)

# 8.5 Actions to address risks and opportunities (ISO 8.5.1 – 8.5.2)

## 8.5.1 Identification of risks and opportunities for improvement (ISO 8.5.1 a – e)

The department operates in accordance with **SG-MPOL-044** Risk Management Policy and **SG-MPOL-052** Clinical Risk Management to identify and manage risk and opportunities for improvement within the laboratory .The department reports preventative action as part of its risk and incident management policy (**SG-MPOL-045** Incident Management Policy and Procedure) using the Q-Pulse non-conformance log or the DATIX application. All corrective actions are reviewed and recorded at monthly incident meetings.

Quality Indicators will be reviewed and monitored on a monthly basis at the DepartmentalQuality Group Meeting as per **SG-MPOL-040** Quality Indicators; indicators cover pre-examination, examination, and post-examination phases and allow for assessment of service Quality and Improvement.

Where an opportunity for improvement is identified, this can be taken forward via change request, change control or staff suggestion as per **SG-MPOL-003**, **SG-MPOL-028** and **SG-MPOL-045**. These are discussed at monthly quality management meetings and may be added to the departmental quality objectives pending agreement at Senior Staff Meetings **SG-MREC-096** Senior Staff meeting Agenda) and the annual management review (**SG-MREC-106** Annual Management review agenda)

## 8.5.2 Acting on risks and opportunities for improvement

For each risk identified by the laboratory, controls will be implemented to reduce the severity of the harm and/or reduce the likelihood of occurrence. The level of risk is calculated in accordance with SG-MPOL-044 and SG-MPOL-052 and is used to prioritise corrective action and improvement to reduce the risk; SG-MPOL-045 Incident Management policy and procedure describes how potential risk is calculated and recorded for all non-conformances raised within the Q-Pulse CAPA module.

Action taken to reduce risk to patients is recorded using **SG-RA-G028** – Clinical Risk Assessment Template and action taken to assess risk to personnel is recorded in the associated documentation for the process/activity. All records are stored within Q-Pulse.

The laboratory reviews the effectiveness of risk controls as part of audit (internal and external), change control, review of clinical, and health and safety risk assessments and incident reporting as described in *Table 1. Risk Identification processes* within SG-MPOL-052 Clinical Risk Management. The Department is committed to continual improvement as described in SG-MPOL-024 Procedure for the management of Evaluation & Continual Improvement.

# 8.6 Improvement (ISO 8.6.1 – 8.6.2)

## 8.6.1 Continual Improvement (ISO 8.6.1 a – e)

The processes associated with continual quality improvement within the department are described in **SG-MPOL-024** Procedure for the management of Evaluation & Continual Improvement. Improvement activities shall be directed to areas of highest risk, management of risk is described in **SG-MPOL-044** Risk Management and **SG-MPOL-052** Clinical Risk Management.

The laboratory has identified a number of Key Performance Indicators (KPI’s) that are used to measure laboratory performance against benchmark criteria as defined in **SG-MPOL-040** -Quality Indicators. Quality Indicators and Performance Assessment is broken down into pre-examination, examination, and post-examination phases as a framework for the internal audit program and for the assessment of service Quality and Improvement and the setting of Quality Objectives and Plans. These audits are recorded in the Q-Pulse audit module and the following documents further describe these continual improvement processes and how findings are reported: These processes are further described in:

* **SG-MPOL-025** - Policy and Procedure for Departmental Audits
* **SG-MPOL-045** - Incident management policy

The Laboratory management team conduct an annual review of the quality management system in accordance with **SG-MPOL-006** - Annual Management Review Policy during which the annual quality objectives and plans (**SG-MPOL-041**) are reviewed and agreed for the following year. The quality objectives are also reviewed for progress at quarterly Senior Staff Meetings (SSM) in accordance with **SG-MREC- 096** - QEUH Senior Staff Meeting Agenda.

Effectiveness of improvement actions is also discussed as a standing agenda item at the AMR and may include, but is not limited to:

* review of any change control implemented as corrective action
* review of clinical risk assessments and residual risk
* review of Short Life Working Group (SLWG), quality improvement projects and risk audit outputs

Improvement plansare communicated to staffvia minutes of departmental meetings, AMR (**SG-MREC-047**) and quality objectives and plans (**SG-MPOL-041**) which are distributed to staff on Q-Pulse. Quality Objectives and plans are also displayed on the departmental Quality notice board.

## 8.6.2 Laboratory patients, users and personnel feedback

Prior to the various staff group meetings, (**SG-MREC-36, SG-MREC-088, SG-MREC-089**), staff are given the opportunity to add items/topics to the agenda for discussion. The daily huddle provides an opportunity for staff to discuss suggestions (**SG-MREC-051**). Suggestions are also raised using the non-conformance module on Q Pulse, via the Employee Suggestion ‘tag’. These suggestions are then discussed at the next general staff meetings and monthly quality meeting. The response and explanation will then be tracked via Q Pulse and recorded in the minutes of the meeting(s).

This is achieved through user liaison (informal and formal), meetings and discussions, communications, and from user surveys (if required), 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.

User needs are formally evaluated and requirements are translated into objective setting and planning(**SG-MPOL-041**) within the QMS. User requirements are also discussed at departmental Senior and General Staff Meetings when appropriate. Summary reports relating to user requirements, associated performance objectives and improvements form a standing agenda item at the AMR (**SG-MPOL-006** Annual Management Review Policy).

# 8.7 Nonconformities and corrective actions (ISO 8.7.1 – 8.7.3)

All nonconformity is reported and managed using non-conformance module in Q-Pulse as described in **SG-MPOL-045** Incident Management policy; this policy also contains information on use of additional reporting systems (e.g. DATIX, SHOT/SABRE).

Non-conformance training is delivered using **SG-CA-G008** QMS and Q-Pulse competency assessment and **SG-WI-G019** Raising and Completing Non-Conformances in Q-Pulse – Quick Guide is available to assist personnel when reporting nonconformity in Q-Pulse.

The process of corrective action, including monitoring and evaluating the effectiveness of implemented corrective action is defined in **SG-MPOL-045** and **SG-MPOL-052** Risk Management Policy.

# 8.8 Evaluations

## 8.8.1General (ISO 8.8.1)

Evaluations are planned covering pre-examination, examination and post-examination processes. Coverage of all phases ensure that the needs/requirements of patients and users are met.

## 8.8.2 Quality indicators (ISO 8.8.2)

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 described in **SG-MPOL-040** - Quality Indicators which are reviewed at the monthly quality meeting and the senior staff meetings

## 8.8.3 Internal Audit (ISO 8.8.3.1 - 8.8.3.2)

The department uses a risk-based approach to audit as defined in **SG-MPOL-025** - Policy and Procedure for Departmental Audits. The Quality Manager, in consultation with the Management Team and Senior BMS staff, is responsible for scheduling internal audits and for ensuring that audits have been conducted in accordance with defined procedures. Planned Audits are scheduled on the internal audit schedule [\\xggc-fsrv-04\GGC Haematology\QEUH\QEUH QMS\Audit\Audit schedule](file:///%5C%5Cxggc-fsrv-04%5CGGC%20Haematology%5CQEUH%5CQEUH%20QMS%5CAudit%5CAudit%20schedule). The risk rating assigned to each audit drives scheduling thereby ensuring audits are prioritised appropriately.

The Departmental Policy details procedures for audit that ensures internal audit is conducted by authorised personnel who are trained and competence assessed in audit technique, and where possible, by personnel independent of the area or process being audited.

The Internal audit program covers both laboratory sites of the department (QEUH and VACH) and is designed to cover the department’s scope in relation to the ISO 15189:2022 standards and the BSQR as detailed in **SG-MPOL-025**- Departmental audit and clinical governanceand includes the following areas:

* Pre-analytical processes
* Post Analytical Processes
* Analytical Processes
* Training and Competency
* Referral Services
* Quality Control and Quality Assurance
* Organisation

There are various KPI outputs which can trigger unscheduled/risk audits including, but not limited to staff suggestions, complaints, non-conformance and audit findings and/or observations. KPIs are a standing agenda item at monthly quality meetings and additional risk audits can be agreed at this meeting. Risk audits are added to the internal audit schedule and Q-Pulse audit calendar.

A series of standardised checklists and templates are used to provide a structure for the audits:

**SG-FORM-G041** - Horizontal Audits

**SG-FORM-G038** - Vertical audits

**SG-FORM-G045** - Examination Audits

**SG-FORM-G074** - Scope Audits

These ensure a comprehensive audit of all processes and activities within the department.

All audits carried out within the department are recorded within Q-Pulse. The completed audit form/checklist is uploaded to the audit record and reviewed by the Quality Manager for completion. Records of internal and external audits are retained in accordance with **SG-MPOL-004** Policy & Procedures for the Control of Process and Quality Records.

# 8.9 Management reviews (ISO 8.9.1 – 8.9.3)

The Laboratory management team conduct an annual review of the Laboratories Quality Management System and all the services it offers in accordance with **SG-MPOL-006** Annual Management Review Policy.

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

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

The review includes the assessment of opportunities for improvement and the need for any changes to the quality management system; this includes updating the quality policy (**SG-MPOL-035**) and quality objectives (**SG-MPOL-041**) and evaluating the laboratory’s contribution to patient care.

The conclusions from the management review will be incorporated into documents that summarise any decisions made and actions agreed during the management review in relation to the following:

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

Actions will be implemented within an agreed time scale. The results of evaluations and processes will available to staff and users. The output of the AMR is recorded within **SG-MREC-047** Annual Management Review minutes which includes the individual sector manager reports. The AMR minutes are retained within Q-Pulse and distributed to all laboratory personnel.

# Appendices

## Appendix 1: Referenced Documents

SG-EXT-G017: Mandatory Induction Standards for Healthcare Support Workers

SG-EXT-G018: Business Continuity Template

SG-EXT-G019: NHSGGC Confidentiality Policy

SG-EXT-G020: Technical Service Manager Job Description

SG-EXT-G021: Laboratory Sector Manager Job Description

SG-EXT-G022: Quality Training Point of Care Manager Job Description

SG-EXT-G023: Technical/Haemoglobinopathy Manager Job Description

SG-EXT-G028: NHS GGC Policy for the safe transport and disposal of samples

SG-FORM-G011: Equipment Fault and Downtime form

SG-FORM-G013: Daily Huddle Form

SG-FORM-G014: Reflective Practice form Incidents

SG-FORM-G071: Incident Investigation and Risk Form

SG-FORM-G017: Departmental Induction Form

SG-FORM-G022: Permit to Work Form

SG-FORM-G026: Calculated Measurement of Uncertainty Values

SG-MPOL-001: Quality Manual

SG-MPOL-003: Policy for Document Control

SG-MPOL-004: Policy and Procedures for the Control of Process and Quality Records

SG-MPOL-005: Policy and Procedures for the Control of Clinical Material

SG-MPOL-006: Policy for Annual Management Review

SG-MPOL-007: Personnel Management

SG-MPOL-008: Training, Education and Development Policy

SG-MPOL-009: Health and Safety Policy and Procedure

SG-MPOL-010: Departmental Induction Policy

SG-MPOL-011 Policy and Procedure for the Procurement and Management of Equipment

SG-MPOL-012: Policy and Procedure for the Management of IT Systems, Electronic Data and Information

SG-MPOL-013: Policy for the Procurement and Management of Supplies, Reagents, Calibration and Quality Control Material

SG-MPOL-014: Policy and Procedure for Sample Reception

SG-MPOL-015: Policy and Procedure for Sample Referral

SG-MPOL-016: Policy for the Selection and Validation of Examination Procedures

SG-MPOL-019: Policy for Specimen Transportation

SG-MPOL-020: Policy and Procedures for Staff and Visitors

SG-MPOL-022: Policy and Procedure for the Management of a Service Level Agreement

SG-MPOL-023: Policy and Procedure for Quality Assurance.

SG-MPOL-024: Procedure for the Management of Evaluation and Continual Improvement.

SG-MPOL-025: Policy and Procedure for Departmental Audits

SG-MPOL-026: Policy and Procedure for Reporting Complaints

SG-MPOL-028: Change Control Policy and Procedure

SG-MPOL-031 Verification and Selection of MSC Third Party Suppliers

SG-MPOL-034: Business Continuity Plan

SG-MPOL-035: Departmental Quality Policy

SG-MPOL-037: Policy and Procedure for Calibration, Metrological Traceability and Measurement of Uncertainty

SG-MPOL-038: Policy and Procedure for the Validation of Equipment

SG-MPOL-039: User Handbook

SG-MPOL-040: Quality Indicators

SG-MPOL-041: Quality Objectives

SG-MPOL-043: Reporting of Results

SG-MPOL-045: Incident Management Policy and Procedure.

SG-MPOL-049: GGC Haematology South Sector policy on the use of, and reference to, UKAS Accreditation, logos and Symbols.

SG-MPOL-051: GGC South Sector Haematology Compliance with Appendix C of UKAS Document Gen 1

SG-MPOL-052: Clinical Risk Management

SG-MREC-036: Senior Staff Meeting Minutes

SG-MREC-037: General Staff Meeting Minutes

SG-MREC-039: QEUH Haem/BT Quality Group Meeting minutes

SG-MREC-068: MSC Steering Group Meeting Minutes

SG-MREC-047: Annual Management Review

SG-MREC-048: Hospital Transfusion Committee Meeting Minutes

SG-MREC-049: Overarching Transfusion Committee Meeting minutes.

SG-MREC-050: Incident Meeting Minutes

SG-MREC-051: Daily Huddle Summary

SG-MREC-052: Diagnostics Clinical Governance Meeting Minutes

SG-MREC-069: MSC Haematology Subgroup meeting minutes

SG-MREC-070: Haematology Management Team Minutes

SG-MREC-071: Haematology Technical Senior Staff Minutes

SG-MREC-088: Blood Bank Delivery Team Meeting Minutes

SG-MREC-089: HCSAP Meeting Minutes

SG-REF-G004: Quality Management and Compliance Group Meetings

SG-REF-B004: The Blood Safety and Quality Regulations 2005

SG-REF-G009: NSS Conduct policy

SG-REF-G024: RCPath/IBMS Retention and Storage of pathological records and specimens

SG-REF-G026 NHSGGC Induction Policies

SG-REF-G027: NHSGGC Complaints Policy

SG-REF-G041: BEIS Policy: National Accreditation Logo and Symbols: Conditions for use by UKAS and UKAS accredited organisations

SG-SOP-TEMP: SOP Template

SG-SOP-G005: Referring Samples to another laboratory

SG-SOP-G008 Revised Report

SG-SOP-G010: Instructions on how to complete SOP Template

SG-SOP-G012: Paediatric and Adult Haematology Reception

SG-SOP-B025: Blood Bank Sample Reception

SG-SOP-B016: Sample referral to SNBTS

SG-SOP-G016: Departmental IT procedures for Telepath

SG-VAL-G001: Validation Report Template

SG-TRAIN-G026: Introduction to Quality and Root Cause Analysis

UKAS Publications: TPS 41, 47, 53 and 57

UKAS Publications: LABS: 1,5,11, 12, 14 and 15

UKAS Publications: Gen 1, Gen 4.

## Appendix 2 – SG-MPOL-035 Quality policy

