**QUALITY MANUAL**

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# Abbreviations and Acronyms

|  |  |
| --- | --- |
| AGM | Assistant General Manager |
| AMR | Annual Management Review |
| BSQR | Blood Safety and Quality Regulations |
| CPD | Continuing Professional Developement |
| EQA | External Quality Assessment |
| HCPC | Health and Care Professions Council |
| HSE | Health and Safety Executive |
| 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 |
| SLA | Service Level Agreement |
| SLM | Sector Laboratory Manager |
| SNBTS | Scottish National Blood Transfusion Service |
| SOP(s) | Standard Operating Procedure(s) |
| TP | Transfusion Practitioner |
| TSM | Technical Services Manager |
| UKAS | United Kingdom Accreditation Service |
| VACH | New Victoria Ambulatory Care Hospital |

# 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: 15189-2012 –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.

The sections of this Quality Manual are arranged so that they equate with the sections in ISO:15189. After the title of each section or sub section, the relevant standard is referenced in brackets (X.X.X.). 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 [SG-ABC -XXX]. The full title of the document can be found in the appendices. 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.

## 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.

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.

## NHSGGC Mission statement

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

## Objectives

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

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

## Scope

This quality manual describes the quality management system of the Department of Haematology, South Glasgow Sector**.**

Its scope is:

* **Internal use:** To communicate to staff the laboratory’s quality policy and quality objectives, to make the staff familiar with the processes used to achieve compliance with quality requirements. This 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.

# 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.

# Organisation and Management Responsibility (4.1)

## Organisation (4.1.1. and 4.1.1.1.)

The laboratory ensures to deliver quality results in a timely manner according to ISO:15189 and the BSQR.

### Legal Entity (4.1.1.2.)

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)

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, 1st Floor

Grange Road,

Glasgow G42 9LF

Telephone: 0141-347-8141

### Ethical Conduct (4.1.1.3.)

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

Laboratory management ensures the following:

* There are no activities that could compromise laboratory performance.
* There are appropriate procedures to ensure ethical respect of patient samples and confidentiality of patient information. (SG-MPOL-005, SG-MPOL-012, SG-EXT-G019, SG-REF-G009)
  + Duties and responsibilities of laboratory personnel are defined.
  + Appropriate communication is established within the laboratory.
  + A quality manager and a health and safety officer aredesignated.
  + Quality, continual improvement and user satisfaction are the personal responsibility of all departmental staff.

### Laboratory Director (4.1.1.4.)

There is one lead clinician for South Sector, and they report to the head of service. Each clinician may have additional duties as outlined in their job description/job plan.

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

|  |  |  |
| --- | --- | --- |
| **Duty** | **Responsibility** | **Comment** |
| Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities. | Lead clinician, TSM, SLM 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. | Lead clinician, 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. | Lead clinician, 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] |
| Serve as a contributing member of the medical staff for these facilities served, if applicable and appropriate. | Lead Clinician | Detailed in this document |
| Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results. | All Consultant medical and registrar staff. | Medical staff are available 24 hours a day. |
| Select and monitor laboratory suppliers | Diagnostic management team. | Controlled through managed service contract. |
| Select referral laboratories and monitor the quality of their service. | TSM, SLM, Technical Leads and Quality Manager | All referral labs are asked to complete evaluation form annually. [SG-FORM-G034] |
|  |  |  |
| **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. | Lead clinician, TSM, SLM, Technical leads, Quality Manager, Transfusion practioner | 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. | Lead clinician, TSM, SLM, Technical Leads and Quality Manager. | Audit module in QMS, Laboratory Non Conformance Log Spreadsheet, Incident, quality and HTC meetings. |
| Address any complaint, request or suggestion from staff and/or users of laboratory services. | Lead clinician, 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. | Lead clinician, TSM, SLM, and Technical Leads | [SG-MPOL-034]  (SG-EXT-G018) |
| Plan and direct research and development, where appropriate. | Lead clinician, TSM, SLM, and Technical Leads. |  |

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### Organisational charts

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

The laboratory and the Diagnostics Division organisation is shown in the organisational charts below:

#### Diagnostics Division

#### Department of Haematology

## Management responsibility (4.1.2.)

### Management Commitment (4.1.2.1.)

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]
* Communicating the regulatory and accreditation requirements [SG-MREC-037 and SG-MREC-039]
* Establishing the quality policy [SG-MPOL-035]
* Ensuring that quality objectives and planning 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

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

The needs of the users of the department are translated into requirements, which form the focus of objective setting and planning. The needs of the users are kept under constant review, achieved through periodic meetings [SG-MREC-048] [SG-MREC-050], [SG-MREC-046] informal discussion and communication, and from user surveys (when deemed necessary).

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

### Quality Policy (4.1.2.3.)

The Quality policy [SG-MPOL-035] of the Haematology department is in appendix 2 of this quality manual.

### Quality Objectives and Planning (4.1.2.4.)

The quality objectives [SG-MPOL-041] for the Directorate are discussed, agreed and documented at the Annual Management Review meeting between the senior management team in Haematology and the Clinical Lead and senior Diagnostics Directorate staff. The Laboratory Management Team defines the quality objectives of the laboratory and is responsible for ensuring that plans are made to meet these objectives.

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

Clinical Head of Service: Dr Edward Fitzsimons (Deputised by fellow Consultants).

General Manager: Isobel Neil.

Assistant General Manager: Jane Gibb, reports to general manager.

Lead Clinician: Dr Ian MacDonald (Deputised by Dr Rajesh Gottipati) reports to clinical head of service

Technical Services Manager (TSM): Tom Moffat (Deputises for AGM as approriate) reports to assistant general manager (Jane Gibb).

Sector Manager (SLM): Claire McKie, (Deputises for TSM & QM) reports to TSM.

Training, Quality and Point of Care Manager (QM): Maureen McBrearty, reports to SLM, accountable to TSM.

Haemoglobinopathy Manager: Mr Iain Fergus: Named deputy- Miss Jacqueline Fellowes.

|  |  |
| --- | --- |
| Sector Lead Clinician | The Sector Lead Clinician has overall clinical responsibility for the Department, and specific responsibility for medical staff recruitment. |
| Consultant Medical Staff | Consultant Medical Staff have responsibilities for Clinical and Laboratory Haematology services and as defined in Job Plans, are accountable to the Sector Lead Clinician. |
| Technical Services Manager | The Technical Services Manager has specific accountability for laboratory operations of the Department. In addition, in conjunction with the General and Assistant General Manager, the Technical Services Manager has accountability for financial operations of the Department.  In the absence of the Technical Services Manager, the Sector Laboratory Manager shall assume responsibilities. [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] |

See also section 3.1.4.1 and 3.1.4.2

### Communication (4.2.1.6.)

The management ensures appropriate communication takes place to keep staff members informed. Meetings are held covering various aspects of the function of the laboratory. Minutes are taken of these meetings and are made available.

#### Departmental Meetings

##### Daily Huddle

A general Staff ‘huddle’ is held daily Monday-Friday @ 08:45 to facilitate 2 way sharing of information amongst staff in a short time frame. (SG-FORM-G013) Following the general huddle, haematology/haemostasis and blood transfusion each hold separate huddles to disseminate and exchange information specific to each section. Each day, a sheet summarising all of the relevant information collated from all 3 huddles is sent to all staff via e-mail. (SG-MREC-051)

##### General Staff Meeting

General Staff Meetings are held monthly for all personnel in the laboratory.

During the meetings:

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

Minutes and Action Points are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SG-MREC-037].

##### Quality Meeting

Quality Meetings are held monthly and senior laboratory staff attend.

During the meetings:

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

Minutes are taken, distributed to the members of the group, and made available on the laboratory’s QMS system [SG-MREC-039].

##### Incident Meetings

Laboratory/Clinical Incident Meetings are held monthly where Clinical Representation from the following Areas are invited to attend: Children’s Cardiac Theatre, Maternity, and Adult Theatres.

During the meetings:

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

Minutes and Action Points are taken of the meeting and these are distributed to the members of the group, and made available on the laboratory’s QMS system [SG-MREC-050].

Where Required, Laboratory only incident meetings will be held in the intervening two weeks between the monthly meetings. Information and any Action points are uploaded to Datix as required and communicated to staff via the daily huddle.

##### Senior Staff Meetings

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

During the meetings:

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

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SG-MREC-036].

##### Technical Senior Staff Meetings

Technical Senior Staff meetings are held monthly. During these meetings the following topics are discussed:

* Staffing
* Training and Staff Rotation
* General operational matters.

Minutes are taken of the meetings; these are distributed and made available on the Laboratory’s QMS system [SG-MREC-071]

##### Hospital Transfusion Committee Meetings

Hospital Transfusion Committee Meetings are held quarterly: for senior Transfusion personnel in the laboratory together with representatives from various clinical areas, and SNBTS.

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SG-MREC-048].

#### Non Departmental Meetings

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

##### Haematology Management Team Meeting

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

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

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SG-MREC-070]

##### Quality Management and Compliance Meeting

Pan-GGC, Pan Disciplinary Quality Management and Compliance Meetings are held bi-monthly and all Quality Management personnel may attend.

During the meetings:

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

Minutes are taken of the meeting these are distributed and made available on the laboratory’s QMS system [SG-REF-G004].

##### Overarching Transfusion Committee

Overarching Transfusion Committee: This occurs quarterly and is for senior blood transfusion management level laboratory and clinical staff on a Pan GGC Basis. Minutes are made available on the laboratory’s QMS system (SG-MREC-049)

##### NHSGGC Point of Care Committee

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

During the meetings:

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

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

##### Clinical Governance Meetings

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

During the meetings:

* Information on clinical incidents is communicated.
* Clinical Effectiveness , Complaints, Risk, BSQR, ISO15189 actions and projects at a divisional level is discussed and communicated.

Minutes are taken of the meeting these are distributed to the attendees. These are available on Q Pulse (SG-MREC-052)

##### MSC – Haematology Subgroup

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

During the meetings

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

Action points are taken at the meeting these are distributed to the attendees. Minutes are held on Q Pulse (SG-MREC-069)

##### Haematology Finance Meeting

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

During the meetings

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

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

##### Greater Glasgow and Clyde IM & T Strategy Group.

Kenny Birney GG&C Laboratory IT Manager attends this meeting and reports back via the Haematology Management Team meeting as described above.

## Quality Manager (4.1.2.7)

The Quality Manager has delegated responsibility and authority to include:

* Ensuring that processes needed for the Quality Management System are established, implemented, and maintained;
* Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;
* Ensuring the promotion of awareness of users’ needs and requirements throughout the laboratory.

# Quality Management System (4.2)

## Documentation (4.2.2.1)

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

* Quality manual [SG-MPOL-001]
* Quality policy [SG-MPOL-035]
* Quality objectives [SG-MPOL-41]

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

## Quality Manual (4.2.2.2.)

This document [SG-MPOL-001] contains:

* The quality Policy [SG-MPOL-035] see appendix 2
* The scope of the quality management systems
* The organisational structure. See sections 3.1.4.1 and 3.1.4.2
* The roles and responsibilities of laboratory management. See section 3.2.5
* The structure and relationships of documents within the QMS
* The managerial and technical activities that support the QMS

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

# Document Control (4.3)

The policy on document control is contained within document [SG-MPOL-003].

Standard document templates [SG-SOP-TEMP, and SOP-SOP-G010] 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 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.

# Service Agreements (4.4)

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

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.

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. [SG-MPOL-022]

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.

# Referral Laboratories (4.5)

## Selection and Evaluation (4.5.1.)

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 the user handbook [SG-MPOL-039].
* 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.

## Results from Referral Laboratories (4.5.1.)

The procedure documents [SG-SOP-G005],and [SG-SOP-B016] 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.

# External Services and Supplies (4.6)

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

NHSGGC operates a system of strict budgetary control. In accordance with Standing Financial Instructions 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.[SG-MPOL-031]

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.

# Advisory Services (4.7)

The Department provides a comprehensive routine and specialised Haematology, Haemostasis, Blood Transfusion and Haemato-Oncology service to service users within and outwith 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 the Service User Handbook [SG-MPOL-039] available on StaffNet or electronic copy. This includes:

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

# Complaints (4.8)

The departmental Policy for Complaints [SG-MPOL-026] and the NHSGGC Complaints Policy [SG-REF-G027] 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. Details about this service are available on the NHSGGC website. If still not satisfied with the response or resolution they then have the opportunity to refer the issue to the Ombudsman.

# Identification and Control of Nonconformities (4.9)

Non conformances are reported and managed using the CAPA module on Q Pulse. The document [SG-MPOL-027] describes the process.

# Corrective Action (4.10)

The department reports corrective action as described in the document [SG-MPOL-027] using the non conformance log or the DATIX application. All corrective actions are reviewed in the incident meetings as part of the review of the non conformance or incident.

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

To assist with Root Cause Analysis, the laboratory utilises the forms [SG-FORM-G012 and SG-FORM-G014].

# Preventative Action (4.11)

The department reports preventative action as part of its risk and incident management policy [SG-MPOL-027] using the non conformance log or the DATIX application. All corrective actions are reviewed in the incident meetings.

# Continual Improvement (4.12)

Quality Indicators and Performance Assessment is broken down into pre-analytic, analytical, and post-analytical 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. The documents [SG-MPOL-024], [SG-MPOL-027] and [SG-MPOL-025] contain the details of the processes to be found and how findings are reported.

# Control of Records (4.13)

The Department utilises a procedure for the identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records [SG-MPOL-004], [SG-MPOL-003], [SG-MPOL-012] to ensure that records are created concurrently with performance of each activity that affects the quality of the examination.

# Evaluation and Audits (4.14)

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

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

## User Feedback (4.14.3)

This is achieved through user liaison (informal and formal), meetings 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 planningwithin in the Quality Management System. 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 Annual Management Review Meeting.

## Staff Suggestions (4.14.4)

Prior to general staff meetings staff hold an informal meeting to discuss points and suggestions to be raised at the general staff meeting [SG-MREC-36]. The daily huddle provides an opportunity for staff to discuss suggestions [SG-MREC-051]

## Internal Audit (4.14.5)

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

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

The departmental internal audit programme is detailed in [SG-MPOL-025]and includes the following areas:

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

A series of standardised checklists are used to provide a structure for the audits.

In addition there are templates that allow for the reporting of other audit types: Horizontal Audits, Vertical audits, Examination Audits and Non Conformance Follow up Audits. Together these allow for comprehensive audit of all processes and activities within in the department

## Risk Management (4.14.6)

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

This is managed by the monitoring and recording of DATIX incidents and by the monitoring and recording of non conformance in the Non-Conformance Log. Records and incidents are monitored on a regular basis by the monthly incident meeting, senior staff meeting, the Hospital Transfusion Committee meeting and additionally the Diagnostics Division Clinical Governance meeting. See sections 3.3.4.1 and 3.3.4.2.

## Quality Indicators (4.14.7)

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

All Laboratory processes are continually monitored and where necessary corrective and preventive action is taken. The laboratory has established quality indicators (SG-MPOL-040) and these are reviewed at the monthly quality meeting and the senior staff meetings

## Reviews by External Organisations (4.14.8)

The department is subject to visits from external accredited organisations. These include UKAS and the MHRA. All visits and any required corrective and/or preventative actions required are currently recorded in the non conformance log.

# Management Review (4.15)

The Laboratory management team conduct an annual review of the Laboratories Quality Management System and all the services it offers.[SG-MREC-047]

## Review Input (4.15.2)

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.

Records of the review are kept of the review and objectives set for the following 12 months.

## Review Activities (4.15.3)

This includes the assessment of opportunities for improvement and the need for any changes to the quality management system. This includes updating the quality policy [SG-MPOL-035] and quality objectives [SG-MPOL-041] and evaluating the laboratory’s contribution to patient care.

## Review Output (4.15.4)

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.

# Personnel (5.1)

The department follows NHS Greater Glasgow and Clyde personnel management policies and procedures for staff recruitment and selection, grievance procedures and staff disciplinary action. 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].

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

## Personnel Qualifications (5.1.2)

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

## Job Descriptions (5.1.3)

Each member of staff has a job description which includes:

* Job title
* Location within the organisation
* Accountability
* Main purpose of the job
* A description of duties and responsibilities
* A requirement to participate in staff annual joint review
* Participation in a CCPD scheme relevant to their role

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

## Personnel introduction to the organizational environment (5.1.4)

All new staff members must complete the corporate and local induction programmes detailed in [SG-REF-G026, SG-MPOL-010] and recorded on [SG-FORM-G017] All Biomedical support workers must complete the Healthcare Support workers Handbook [SG-EXT-G017] and acknowledge the healthcare support workers code of conduct. All grades of staff are expected to complete the relevant GMP and other associated Blood Transfusion modules on learn Pro.

## Training (5.1.5)

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

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

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

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

All senior biomedical scientist staff are expected to act as mentors and supervise staff in training.

There is a training manager and a training officer for Haematology and Blood transfusion.

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

* Registration portfolio for trainees
* Specialist Portfolio
* Mandatory training for all staff
* Access to library and information services
* Athens logins are available to all staff
* Attendance at meetings and conferences
* Financial support
* Time for CPD for qualified staff
* Patient confidentiality and ethics
* Health and Safety
* Departmental Processes
* The QMS

Records are kept of all training and education.

## Competency Assessments (5.1.6)

The department performs competency assessments and training and competency programmes are in place. The standard training and competency programmes can be found in Q. Pulse.

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

At the time of writing this policy, it is envisaged that Staff competency assessments will located on Q-Pulse within the staff member’s record. However, there may be some paper records still held in the individual’s training folder.

## Reviews of Staff Performance (5.1.7)

An annual joint review is held with each staff member and their designated reviewer. All staff performing annual joint reviews have been trained and those staff participating have had a full explanation of the process. The process is currently recorded using the eKSF system; in April 2018 this will change to Turas.

The annual joint review includes:

* Objectives and plans for the Laboratory
* Job description of the Staff Member
* Personal objectives of the Staff Member
* Training and development needs of the Staff Member

## Continuing Education and Professional Development (5.1.8)

All staff are expected to participate in CPD. Additionally there is a requirement from the registration body (HCPC) that registrants must maintain CPD. To aid them in the maintenance of CPD records staff are encouraged to upload evidence of CPD activities to their record on Q-Pulse.

## Personnel Records (5.1.9)

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

Staff records held include:

* Personal details
* Employment details
* 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.

# Accommodation and Environmental Conditions (5.2)

The department provides routine and specialised services from 2 sites situated at:

* QEUH
* VACH

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

## Laboratory and Office Facilities (5.2.2)

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

The Laboratory has adequate space for:

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

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

Visitors to the Laboratory must be accompanied by Laboratory Staff at all times and must abide by the rules for visitors [SG-MPOL-020].

## Storage Facilities (5.2.3)

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

Temperature controlled facilities include:

* Cold rooms
* Refrigerators
* Freezers
* Blood Fridges

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

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

Additional storage facilities exist for:

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

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

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

## Staff Facilities (5.2.4)

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

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 study areas at QEUH with printing and internet facilities.

## Patient Sample Collection Facilities (5.2.5)

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

Advice on sample types, labelling requirements and other relevant information is available in the departmental user’s handbook [SG-MPOL-039].

## Facility Maintenance and Environmental Conditions (5.2.6)

The laboratories are maintained to provide a functional and safe work environment. All work areas are kept clean and well maintained. Any deficiencies or defects are reported using the online reporting facility or via telephone.

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.

In addition all staff are distributed a copy of the health and safety policy and procedure [SG-MPOL-009]

# 0 Laboratory Equipment Reagent and Consumables (5.3)

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 to [SG-MPOL-013].

## Equipment

### Equipment Acceptance Testing (5.3.1.2)

The department validates equipment prior to use in compliance with the validation policy [SG-MPOL-038] and 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 management policy [SG-MPOL-011]. The results of the acceptance testing are recorded on Q-Pulse [SG-VAL-G001]

### Equipment Instructions for Use (5.3.1.3)

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

Manufacturer manuals are available.

Training and competency assessment records are in place for equipment and can be located on Q. Pulse with completed records uploaded to the staff member’s record.

### Equipment calibration and metrological traceability (5.3.1.4)

All equipment is calibrated on a planned basis by competent personnel. This may be trained local staff but most likely to be 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 line with management policy [SG-MPOL-001].

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

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

### Equipment maintenance and repair (5.3.1.5)

All equipment has 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 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 laboratory staff according to manufacturers/supplier’s recommendations.

Any defective equipment is immediately withdrawn from service and clearly labelled to show that it must not be used. Checks are made to assess if the defective equipment has had any impact upon examinations undertaken prior to the defect being discovered. If it is 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 is maintained.

A Permit to workform [SG-FORM-G022] must be completed prior to an engineer commencing work on any equipment.

### Equipment adverse incident reporting (5.3.1.6)

Adverse incidents associated with the use of equipment are recorded using the Equipment Fault and Downtime form SG-FORM-G011. These are assessed for trends at the quality meetings. In addition any equipment failures which have resulted in the release of incorrect results must be logged via the Datix reporting system. 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.

### Equipment Records (5.3.1.7)

Records for equipment that is located within the department are kept on the Asset 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 but due to the nature of some of the material it is not possible to store them on Q-Pulse. Verification documents and data are stored within the document module of Q-Pulse. This is described within management policies [SG-MPOL-011, SG-MPOL-005, SG-MPOL-038]

As a minimum these 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 is maintained.

## Reagents and Consumables (5.3.2)

The Departmental policy for procurement and Management of Reagents, Calibration and Quality Control Material is described in document [SG-MPOL-013]. These procedures include:

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

### Reception and storage (5.3.2.2)

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

### Acceptance testing (5.3.2.3)

New batches of reagents or kits which have a change in formulation or procedure are verified for performance before they are used for in routine service. A similar approach is adopted for changes in consumables that may affect the quality of examinations.

### Inventory management (5.3.2.4)

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

### Instructions for use (5.3.2.5)

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

### Adverse incident reporting (5.3.2.6)

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

### Records (5.3.2.7)

The department maintains records of reagents and consumables in accordance with [SG-MPOL=013] and [SG-MPOL-004]

# Pre-examination Processes (5.4)

## Information for patients and users (5.4.2)

Information for service users is provided in the service user handbook for the department of haematology [SG-MPOL-039] with access to NHSGGC users via StaffNet and electronic copies available on request for others.

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.

## Request form information (5.4.3)

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

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].

## Primary sample collection and handling (5.4.4)

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

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

Information for service users for the completion of the request (manual or electronic) including sample type and volume is provided in the service user handbook for the department of haematology [SG-MPOL-039]. Information is also displayed on the trakcare system.

### Instructions for collection activities (5.4.4.3)

Information for service users for the completion of the request (manual or electronic) including sample type and volume is provided in the service user handbook for the department of haematology [SG-MPOL-039]. Information is also displayed on the Trakcare system and advice available from the laboratory. Electronic requesting automatically captures required information.

## Sample transportation (5.4.5)

There is an established NHSGGC policy for the transportation of specimens by porters and couriers [SG-EXT-G028] 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

Transport of samples across GGC Sites is governed by the policy [SG-MPOL-019]

## Sample reception (5.4.6)

The overarching policy for sample reception is described in [SG-MPOL-014]. The department follows a separate documented procedure for the discipline specific specimen receptions located within in the laboratory: [SG-SOP-G012, for paediatric and adult Haematology, and SG-SOP-B025 for blood transfusion ] Each of these include instructions for:

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

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

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

# Examination Procedures (5.5)

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

The Departmental Policy and Procedure for Validation of Equipment [SG-MPOL-038], [SG-MPOL-016] and associated documents describe the procedures and requirements for Change Control and the evaluation and performance of validation and verification of processes. All data is uploaded to Q-Pulse.

### Verification of examination procedures (5.5.1.2)

The Departmental Verification Policy [SG-MPOL-038] 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.

### Validation of examination procedures (5.5.1.3)

The Departmental Change Control Policy [SG-MPOL-028] and Verification Policy [SG-MPOL-038] and associated documents describe the procedures and requirements for Change Control and the evaluation and performance the validation of processes. All data is uploaded to Q-Pulse.

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

Uncertainty of measurement estimation for test results have been determined as described in [SG-MPOL-037] {These are recorded on the form [SG-FORM-G026] and in the service user handbook for the Department of Haematology [SG-MPOL-039] to be available to service users.

## Biological reference intervals or clinical decision values (5.5.2)

These are included in the standard operating procedures and in the service user handbook for the department of haematology [SG-MPOL-039] to be available to service users.

## Documentation of examination procedures (5.5.3)

All methods and equipment have standard operating procedures which are stored in Q Pulse. These are controlled documents, which are reviewed biennially or sooner as stated on the document. The requirements and process is described in the QMS policy [SG-MPOL-003].

# Ensuring quality of examination results (5.6)

The Departmental Quality Assurance Policy [SG-MPOL-023] outlines the department’s procedures for quality Assurance.

## Quality Control (5.6.2)

### Quality control materials (5.6.2.1)

Instructions on preparation for use, stability and storage are contained in the SOPs.

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

### Quality control data (5.6.2.2)

IQC reports are discussed at daily huddle where there are any results that impact on the ability of the laboratory to release results. Where possible IQC data is uploaded onto Q-Pulse onto the asset record. There are procedures in place for the assessment of the impact of IQC failure including, re-analysis of samples, amending reports and incident reporting.

## Interlaboratory comparisons (5.6.3)

The Departmental Quality Assurance Policy [SG-MPOL-023] outlines the department’s procedures for quality Assurance.

### Participation (5.6.3.1)

The department participates in EQA schemes that are accredited to ISO:17043 where these are available.

### Alternative approaches (5.6.3.2)

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

### Analysis of interlaboratory comparison samples (5.6.3.3)

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

### Evaluation of laboratory performance (5.6.3.4)

Lab performance is communicated and assessed at the Senior Staff meetings. Discussion is based on IQC and EQA performance for possible systematic and random errors in performance. Cross site review is included. Problems are highlighted, decisions recorded in the minutes and actions agreed. Performance that is out with consensus is discussed at Senior Staff Meetings.

## Comparability of examination results (5.6.4)

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

# Post-examination processes (5.7)

## Review of results (5.7.1)

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

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

The departments stores, retains and disposes of clinical samples in accordance with the requirements of the Human Tissue Act 2004, 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 [SG-MPOL-005, SG-REF-G024 and SG-EXT-G028]

# Reporting of results (5.8)

The department has a policy and procedure for the reporting of results that includes communication [SG-MPOL-043]. Reports are available to all NHSGGC users electronically and to others as a printed copy.

## Report attributes (5.8.2)

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

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

## Report content (5.8.3)

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

Reports include the following:

* The Laboratory performing analysis.
* The unique identity of the patient.
* 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.

# Release of results (5.9)

The departmental procedure [SG-MPOL-043] details the process to be followed.

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.

## Automated selection and reporting of results (5.9.2)

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

## Revised reports (5.9.3)

There is a departmental procedure [SG-SOP-G008] for revising and amending 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.

# Laboratory information management (5.10)

The department has a documented procedure [SG-MPOL-012] to ensure that the confidentiality of patient information is maintained at all times. This is also in compliance with the BSQR and NHSGGC policy [SG-EXT-G019].

## Authorities and responsibilities (5.10.2)

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

* 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

## Information system management (5.10.3)

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

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

The operation of the system is in compliance with data protection legislation, departmental and NHSGGC policies [SG-MPOL-012] [SG-SOP-G016][SG-EXT-G019] and the BSQR.

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

# 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-G012: Incident Action Plan form and RCA

SG-FORM-G013: Daily Huddle Form

SG-FORM-G014: Reflective Practice form Incidents

SG-FORM-G017: Departmental Induction Form

SG-FORM-G022: Permit to Work Form

SG-FORM-G026: Calculated Measurement of Uncertainty Values

SG-FORM-G034: Referral Laboratory Evaluation Form

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-027: Policy and Procedure for Quality Management System Audit Processes and the Identification and Control of Non-Conformities

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-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-046: Primary Care Order Comms User 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-REF-G004: Quality Management and Compliance Group Meetings

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

SG-REF-G009: NHSGGC Code of Conduct for Staff

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-SOP-TEMP: SOP Template

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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

UKAS Publications - TPS 41, 47, 51, 53 and 57

UKAS Publications – LABS: 1, 3, 5, 11, 12, 14, 15 and 36

## Appendix2: Quality Policy

