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| --- |
| **QUALITY MANUAL** |
| **Scope & Purpose of Document** |
| All policies and procedures specified herein are mandatory within the Department.The Quality Manager is responsible for ensuring the implementation and maintenance of this Quality Manual, and in conjunction with the Departmental Management Team and Senior Staff, is responsible for ensuring the implementation and maintenance of policies and associated procedures as specified herein. All necessary definitions shall be provided within the text. |
| **Document Version Changes** |
| Version 17 is updated to version 18 – Updated organisational chart, reference to MP-CGEN-031 - 'POLICY AND PROCEDURES FOR THE MANAGEMENT OF IT SYSTEMS, ELECTRONIC DATA AND INFORMATION' in sections 7.6, sections 8.7 updated to include reference to NC training (MF-CGEN-T-125), section 8.8 updated to include integration of BSH guidelines/gap analysis using MF-CGEN-090 - Guideline gap analysis tool. Lines of communication updated to include all staff communications tools, including SharePoint.  |
| **Document References** | **Related Documents** |
| * ISO 15189: 2022 – Medical Laboratories – Requirements for Quality & Competence
* Blood Safety and Quality Regulations 2005 (“the principal Regulations”) and subsequent amendments,
* Commission Directive 2005/61/EC,
* Commission Directive 2005/62/EC
* EDQM Guide to the preparation, use and quality assurance of blood components
* UKAS Publications - TPS 41, 47, 51, 53 and 57
* UKAS Publications – LABS: 1, 3, 5, 11, 12, 14, 15 and 36
 | The Quality Manual serves, partly, as a directory of Quality Management System documentation. Accordingly, related Quality Management System documents shall be referenced throughout the text. |

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# Introduction

This Quality Manual, together with Policy and Procedure documents to which it refers, serves to define the Quality Management System (QMS) of the Department of Haematology, Clyde Sector, NHSGGC.

All policies and procedures specified herein are mandatory within the Department of Haematology, Clyde Sector, NHSGGC.

This manual defines Departmental compliance with the below standards/legislation:

* BS EN ISO 15189:2022 – Medical Laboratories – Requirements for quality and competence
* The Blood Safety and Quality (Amendment) Regulations 2007 No. 64 (Commission Directive 2005/61/EC, and, Commission Directive 2005/62/EC)
* Good Manufacturing Practice (GMP) **(**[EudraLex - Volume 4 – Good Manufacturing Practice (GMP) guidelines](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en)) and EDQM Guide to the preparation, use and quality assurance of blood components

# General information about the department

Inverclyde Royal Clinical Laboratories are situated on Level C, Inverclyde Royal Hospital site, where the laboratory facility is shared with the Department of Clinical Chemistry.

The Laboratories of Royal Alexandra Hospital are situated in a designated Laboratories Block (Block 2), on the Royal Alexandra Infirmary hospital, where the laboratory facility is shared with the Department of Clinical Chemistry.

The Laboratories of Vale of Leven Hospital are situated on the grounds of Vale of Leven District General Hospital that is shared with the Department of Clinical Chemistry.

Information on services offered at each site can be found on our website at the below location:

 [Clyde Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/clyde-sector-haematology/)

# Introduction to the quality manual

This Quality Manual can be regarded as the index to the Quality Management System. Sections 4 - 8 of this document are arranged to equate with BS EN ISO: 15189:2022 – Medical Laboratories – Requirements for quality and competence standards 4 – 8, for determination of compliance. Cross reference to other applicable standards is also included. Quality management system documents are presented in **BOLD** and associated standards/regulations in **BLUE**.

# General Requirements (ISO 4.0)

* 1. ***Impartiality (*ISO 4.1 a-e*)***

The NHSGGC Code of conduct for staff outlines the ethical conduct expected of staff and can be accessed via the link below. Details of the NHSGGC staff Grievance procedure can also be found using the link below:

[Conduct and Complaints - NHSGGC](https://www.nhsggc.scot/staff-recruitment/hrconnect/policies-and-staff-governance/polices/conduct-and-complaints/)

In compliance with NHSGGC policy the department adheres to NHSGGC Code of Conduct for Staff and Declarations of Interests, Gifts and Hospitality. Further information on this policy is located below:

[Declaration of gifts, hospitality and interests](https://scottish.sharepoint.com/sites/GGC-Finance/SitePages/Declarations.aspx)

Personnel are required to re-confirm their conflict of interest status annually via **MF-CGEN-084** – Annual Declaration of Conflict of Interest.

The Department operates a strict budgetary control and purchasing policy, as outlined within “Standing Financial Instructions”:

[Financial Governance](https://scottish.sharepoint.com/sites/GGC-Finance/SitePages/Financial-Governance.aspx)

* 1. ***Confidentiality (*ISO 4.2.1, 4.2.2, 4.2.3*)***

The Department is required demonstrate compliance with Data Protection legislation and Patient Confidentiality. This is described in documentation below:

* **MP-CGEN-003** – QMS Document & Pathological Records – Storage, Retention & Archive Policy
* **MP-CGEN-003** - QMS Document & Pathological Records – Storage, Retention & Archive Policy – section 5 describes release of records to 3rd parties, using form **MF-CGEN-003** – Release of Specimens or Data to the Police

The potential for information release to 3rd parties is described to service users in **MI-CGEN-091** – Terms and conditions for Service Provision - Statement.

Staff training around confidentiality forms part of NHSGGC mandatory training (**MP-CGEN-019** – Training Policy), and if fulfilled by completion of the below LearnPro module:

* GGC: 009 Safe Information Handling ([Statutory and Mandatory Training - NHSGGC](https://www.nhsggc.scot/staff-recruitment/hrconnect/learning-education-and-training/statutory-and-mandatory-training/))

Further information and advice on use and sharing of clinical information can be found via NHSGGC Caldicott StaffNet site:

[Caldicott (scot.nhs.uk)](http://www.staffnet.ggc.scot.nhs.uk/CORPORATE%20SERVICES/EHEALTH/INFOGOVINDEX/Pages/Caldicott.aspx)

* 1. ***Requirements regarding patients (*ISO 4.3 a-i*)***

The feedback, in all its forms, of Departmental Users is regarded by the Department as an essential mechanism for standard setting and Quality Improvement. Feedback mechanisms are defined below:

* Periodic meetings ([Section 5.4](#_Structure_and_authority))
* Informal discussion and communication ([Section 8.6](#_Improvement_(ISO_8.6)))
* User surveys / questionnaires ([Section 8.6](#_Improvement_(ISO_8.6)))
* Monthly review of requests received by the laboratory ([Section 8.8](#_Evaluations))

**MF-CGEN-022** – Service user handbook provides information on examination process and examination TAT. This is published on the Departmental website at the location below:

[Clyde Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/clyde-sector-haematology/)

The needs of the users are kept under constant review and data gained from above activities used to support selection of examination methods and interpretation of results. User needs and requirements, including complaints, are discussed (see [Section 5.4](#_Structure_and_authority)). Where appropriate, user needs form the focus of objective setting and planning within in the Quality Management System.

The Department operates a Departmental **MP-CGEN-006** – Complaints Policy for assessment and review of complaints. The Department operates within NHGGC 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 described in **MP-CGEN-005** – Risk and Incident Management Policy and Procedure.

NHSGGC operates a comprehensive consent policy ([Consent Policy](http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Key%20Information/Pages/ConsenttoTreatmentPage.aspx)). Consent is inferred when submitting a request to the laboratory.

Information is retained/available to the patient as described in **MP-CGEN-003** – QMS Document & Pathological Records – Storage, Retention & Archive Policy. Patients may request further information using the NHSGGC Freedom of Information Service ([Freedom Of Information (Scotland) Act 2002 (FOISA/FOI) Environmental Information (Scotland) Regulations 2004 (EIRs) - NHSGGC](https://www.nhsggc.scot/contact-us/freedom-of-information-foi/)). The rights of patient to have care free from discrimination is upheld by adherence to NHSGGC ethical (see [Section 4.2](#_General_Requirements)) and NHSGGC Equality, Diversity and Inclusion Policy ([Equality, Diversity and Inclusion NHSGGC](https://www.nhsggc.scot/staff-recruitment/hrconnect/policies-and-staff-governance/polices/equality-diversity-and-gender-based-policies/#equality-diversity-and-human-rights))

# Structural and governance requirements (ISO 5.0)

## Legal entity (ISO 5.1)

The Department of Haematology, Clyde Sector, NHSGGC, a sub-division of the Diagnostics Directorate, Acute Services Division, NHSGGC (see [Section 5.4](#_Structure_and_authority)), comprised of laboratories situated at location below:

|  |  |
| --- | --- |
| **Type of Laboratory:** | **National Health Service Haematology & Blood Transfusion Laboratory** |
| **The Department of Haematology, Clyde Sector, NHSGGC** |
| **Postal Addresses:** | Haematology Laboratory,Royal Alexandra Hospital,Corsebar Road,Paisley, PA2 9PN.Tel 0141 887 9111.Fax 0141 314 6604. | Haematology Laboratory,Inverclyde Royal Hospital,Larkfield Road,Greenock, PA16 0XN.Tel 01475 633777.Fax 01475 635486. | Haematology Laboratory,Vale of Leven Hospital,Main Street,Alexandria, G83 0UA.Tel 01389 754121.Fax 01389 755948. |

## Laboratory Director (ISO 5.21, 5.2.2, 5.2.3)

Structure of the medical team is detailed in [Section 5.4](#_Structure_and_authority), including Laboratory Director. Consultant Haematologist NHSGGC - Job Description Laboratory Director duty/responsibility delegation is contained in [Appendix A](#_Appendix_A_–).

The Laboratory Director is expected to attend (or delegate attendance) the monthly NHS Greater Glasgow and Clyde Haematology Management Team Meeting (HMT). The HMT has overarching responsibility of all laboratories within NHSGGC and will offer support to the Laboratory Director so they can perform associated duties. The Laboratory Director’s defined responsibilities (and those delegated) are contained in [Appendix A](#_Appendix_A_–).

## Laboratory Activities (ISO 5.3.1, 5.3.2, 5.3.4 a-d)

The Department provides a comprehensive routine and specialised haematology service from all hospital sites that comprise the Clyde Sector ([see Section 5.1](#_Legal_entity_(ISO)), as defined in via the **MF-CGEN-022** - Service User Handbook (available via Departmental [Website](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/clyde-sector-haematology/)). Commitment to service quality is defined in **MP-CGEN-007** – Quality Policy (see [Appendix B](#_Appendix_B)).

***Determined in consultation with service users, the Department is committed to the provision of a consultant led clinical advisory and appropriate analytical laboratory out of hour’s service.***

The Departmental Medical Team, led on each Hospital site by a Lead Consultant, provides a clinical consultation service both for hospital inpatients and patients in General Practice.

***Haematology Medical Staff are contracted, (60% WTE) for clinical services, as managed entity of the Division of Regional Services, NHSGGC, and for Laboratory Services (40% WTE), by the Division of Diagnostics, NHSGGC – see*** [***Section 5.4***](#_Structure_and_authority) ***Divisional Management Structure – Haematology, Clyde Sector.***

Rotas (general and specialist), staffed by both middle grade and consultant medical staff, operate for clinical advice, authorisation of blood product usage and issue and discussion of laboratory results. Copies of staff rotas, including contact details, are held by the NHSGGC Telephone Operators.

See also [Section 5.5](#_Objectives_and_policies).

## Structure and authority (ISO 5.4.1 a-c, 5.4.2)

NHSGGC Clyde Haematology Department is formed as a sub-Division of the Division of Laboratory Medicine,NHSGGC*.* The organisational relationships within are defined below:



Departmental Staff – Key Responsibilities

|  |  |
| --- | --- |
| **Laboratory Director** | The 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 Clinical Services 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.  |
| **Sector Manager** | Responsibilities of the Sector Laboratory Manager are defined in **MI-CGEN-011**. Sector Manager has name responsibility for blood transfusion services. Responsibilities include the role of Deputy to the Quality, Training and POCT Manager. |
| **Operations Manager** | Direct deputisation for Sector Manager responsibilities and is defined in **MI-CGEN-112**.  |
| **Quality, Training and POCT Manager** | Responsibilities of the Quality, Training and POC manager are defined in **MI-CGEN-012.** |

Lines of communication

|  |  |  |  |
| --- | --- | --- | --- |
| **Meeting Type** | **Title** | **Frequency** | **Terms of reference summary** |
| NHSGGC Corporate Communications and StaffNet | NHSGGC Email communications | Variable | Communication of NHSGGC Strategy, inclusive of service and or organisational change, via Staff Newsletters, and Team, and Core Brief. |
| Management Meetings | NHSGGC Haematology Management Team (HMT) | Monthly | Administer and review resource, clinical effectiveness and audit within the Department of Haematology, to oversee and align strategy within the Laboratories Directorate. |
| NHSGGC Point of Care Testing (POCT) Committee | Quarterly | Implementation of **MI-CGEN-016** - NHSGGC POCT Policy. The Committee Chair reports to the NHSGGC Diagnostics Clinical Governance Committee |
| Clyde Sector (Multi-Disciplinary) Health and Safety Group | Quarterly | Oversee and align Health and Safety strategy across Diagnostics, Clyde Sector, and to ensure compliance with NHSGGC, and National, Health & Safety policy and practice.  |
| Departmental Meetings | Haematology Management Meeting  | Monthly | Review of services, technical process and quality compliance programmes in the department. |
| Haematology – Senior Staff Meetings (including Quality review) | Monthly | Discuss, evaluate, and to communicate organisational, professional and technical policy and procedures. Quality meeting is also included.  |
| Clyde Sector Haematology – General Staff Meetings  | Monthly | Discuss, evaluate, and to communicate organisational, professional and technical policy and procedures and quality issues.  |
| Blood Transfusion meetings | NHSGGC Overarching Transfusion Committee | Quarterly | Review and ensure commonality in, and to oversee the safety and effectiveness of the Hospital Blood Banking service throughout NHSGGC. |
| Clyde Sector - Hospital Transfusion Team Meetings | Monthly | Review of Blood Transfusion incidents, review Blood Transfusion related performance indicators. Escalation to SHOT/SABRE/NHSGGC SAE where required |
| Clyde Sector - Hospital Transfusion Committee | Quarterly  | Review and oversee the safety, quality and effectiveness of the Hospital Blood Banking / Transfusion service consistent with National and International Blood Banking Legislation and Guidelines, such as the Better Blood Transfusion Program, the Blood Safety & Quality Regulations, UKAS (ISO: 15189), and so on. |
| All staff communications  | TSM communication, departmental memos, email, announcements using SharePoint, Whats app.  | Variable | For distribution of information to all staff covering operations, quality and compliance.  |

Controlled meeting agendas ensure accurate minute keeping, where possible:

* **MF-CGEN-068** – Management Meeting Agenda Form
* **MF-CGEN-078** – Senior Scientist Meeting Agenda Form
* **MF-CGEN-019** – Departmental Meeting Minutes Pro-Forma
* **MF-CGEN-077** – Clyde HTT Agenda Template

Minutes are distributed to relevant staff groups via email or Q-Pulse.

## Objectives and policies (BSQR, ISO 5.5 a-d)

Objectives and policies are defined as below:

|  |  |
| --- | --- |
| **MP-CGEN-007** - Quality Policy | The Quality Policy communicates to staff and users the below:* Meet needs and requirements of patients and users
* Commit to good professional practice;
* Provide examinations that fulfil their intended use;
* Conform to BSI ISO 15189:2022 standards;
* Adhere to BSQR 2005 legislation
 |
| **Objectives**  | Are established locally or within the Diagnostics Directorate. There are set out annually at the Annual management review (**MP-CGEN-015**) and updated as and when required using **QF-CGEN-015** – Quality Objectives and Plans Report Form |

Where feasible objectives will be SMART to measure and determine effectiveness of objectives and policies.

**MP-CGEN-008** - Change Control, Validation and Verification insures the integrity of the management system (objectives and policies) are maintained through periods of change.

Quality indicators in place to monitor performance in relation to objectives are defined in [Section 8.8](#_Evaluations).

## Risk management (ISO 5.6 a-b)

The Department operates **MP-CGEN-005**- Risk & Incident Management Policy that includes a systematic process approach to risk management. The below documentation further details the risk management process in the Department.

**HP-CGEN-001** - Health & Safety Code of Conduct provides procedural information related to Health & Safety risk assessment in accordance with NHSGGC Health & Safety Policy ([Health and Safety Policy (nhsggc.org.uk)](https://www.nhsggc.org.uk/media/269268/health-safety-policy-april-2021.pdf).

**MP-CGEN-029** – Clinical Risk Management provides information on procedures related to clinical risk assessment in alignment with BS EN ISO 22367:2020 - Application of risk management to medical laboratories.

Laboratory director responsibility/delegation of risk management is described in [Appendix A](#_Appendix_A_–).

# Resource requirements (ISO 6.0)

## General (ISO 6.1)

GG&C Diagnostics review and amend staffing levels through workforce planning meetings and an active recruitment process to maintain sufficient staff to provide an appropriate 24/7 service to users.

Facilities are maintained by Abbott as MSc provider along with local estates and facilities teams within GG&C (see **MP-CGEN-023** – Management of Accommodation and Environment Policy).

Equipment is maintained by Abbott as Managed Service Contract (MSC) provider or via the contracted third party suppliers within this MSC. Anything sitting out with the contract is maintained by other service and maintenance contracts (see **MP-CGEN-010** – Management of Equipment).

Reagents are maintained by Abbott as Managed Service Contract (MSC) provider or via the contracted third party suppliers within this MSC. Consumables are maintained by Abbott as Managed Service Contract (MSC) provider or via the contracted third party suppliers within this MSC. Anything out with the contract is provided by the Scottish NDC via Pecos. See **MP-CGEN-011** – Management of Suppliers.

GG&C provides all support services via its e-health, estates, HR, facilities, procurement and recruitment teams. There is also a robust Diagnostic Management structure to support labs.

## Personnel (ISO 6.2)

General (**ISO 6.2.1 a-d**)

Departmental Staffing Plan is reviewed both as on-going routine Departmental Management Team activity and as a standing element of **MP-CGEN-015** - Annual Management Review Meeting.

The Department of Human Resources, NHSGGC, operates a systematic process for the recruitment and selection of staff. This process is defined in the link below:

[The Recruitment Service - NHSGGC](https://www.nhsggc.scot/staff-recruitment/hrconnect/the-recruitment-service/)

All personnel are required to participate in training for all laboratory activities as stipulated NHSGGC Staff Governance Policy:

<http://www.staffnet.ggc.scot.nhs.uk/Human%20Resources/Staff%20Governance/Pages/StaffGovernance.aspx>

Departmental training procedures for all laboratory activities are defined in defined in **MP-CGEN-019** – Training Policy. Department induction and orientation procedures are defined in **MP-CGEN-019** – Training Policy and further information is available below:

[Guidance and Resources for Managers and Supervisors - NHSGGC](https://www.nhsggc.scot/staff-recruitment/hrconnect/learning-education-and-training/induction-portal/guidance-and-resources-for-managers-and-supervisors/)

Departmental induction and orientation is recorded usingforms below:

* **MF-CGEN-024** - New Staff Orientation and Induction
* **MF-CGEN-031** - Cross-site induction
* **MF-CGEN-074** – Staff Orientation form – RAH to IRH

**MF-CGEN-024** – New staff Orientation and Induction states all staff must partake in **MI-CGEN-093** – Quality Management System: An Introduction. This communicates the importance of meeting user needs and adherence to ISO 15189 standards.

Personnel qualifications and competency requirements (ISO **6.2.2 a-d**)

Education and qualification requirements for all roles are defined in associated job descriptions. Qualification records are held in Personnel files as described in **MP-CGEN-020** – Personnel Management.

As defined in **MP-CGEN-019** - Training Policy the departmental core training and rolling competency programme covers all areas influencing laboratory activity results. **HF-CGEN-025** - Risk Assessment - Competency evidence process assesses residual risk in this process. Medical competency procedures is assed as described in **MP-CGEN-024** – Policy for Assessing Competence of Medical Consultants.

Authorization to perform activities (**ISO 6.2.3 a-c**)

Personnel are authorized to perform specific laboratory activities only after appropriate training has been undertaken (**MP-CGEN-019** – Training Policy). Access to LIMS systems is controlled as defined in [Section 7.6](#_Control_of_data).

Associated Examination Procedure SOPs also define the requirement for results validation (authorisation) by specific staff groups.

Review of Staff Performance and CPD programme (**ISO 6.2.4**)

This is defined within **MP-CGEN-019** – Training Policy. Clyde Haematology CPD and Training hub is available to all staff via the website below:

[Clyde Haematology CPD/Training Hub (sharepoint.com)](https://scottish.sharepoint.com/sites/ClydeHaematology/SitePages/CPD-Events.aspx?source=https%3A%2F%2Fscottish.sharepoint.com%2Fsites%2FClydeHaematology%2FSitePages%2FForms%2FByAuthor.aspx)

Personnel Records (**ISO 6.2.5 a-e**)

Procedural information on retention of personnel records is detailed in **MP-CGEN-003** – QMS Document & Pathological Records – Storage, Retention & Archive Policy and **MP-CGEN-019** – Training Policy.

Retention locations of staff records is described in **MF-CGEN-038** – Retention & Storage of QMS Documentation, Process & Pathological Records, and Archives.

## Facilities and environmental conditions (BSQR, ISO 6.3)

See **MP-CGEN-023** – Management Policy for Accommodation and the Environment for further information.

## Equipment (BSQR, GMP, ISO 6.4)

General (**ISO 6.4.1**)

**MP-CGEN-010** – Equipment Policy defines procedures for the selection, purchasing and management of laboratory equipment including:

* The assessment criteria, and justification of need,
* Selection criteria,
* Acceptance and evaluation procedures,
* Equipment Maintenance and Training of staff.

**MP-CGEN-008** - Change Control, Validation and Verification defines departmental procedures relating to the specification of replacement equipment, with reference to the identification of key user requirements, in the form of a User Requirement Specification (URS).

Equipment Requirements (**ISO 6.4.2 a-d**)

Assessment of equipment requirements (URS) for correct performance of laboratory activities is detailed in **MP-CGEN-008** – Change Control, Validation and Verification. **MP-CGEN-010** - Equipment Policy ensures compliance with BSI ISO 15189:2022 are met and details of equipment maintenance procedures.

Equipment acceptance procedure (**ISO 6.4.3**)

Equipment acceptance procedures are defined in **MP-CGEN-008** - Change Control, Validation and Verification. The department will verify that equipment is capable of achieving the necessary performance criteria, pre-determined by the URS to assure compliance with requirements in relation to associated Examination Procedures **PRIOR** to commencing routine laboratory use.

Equipment instructions for use (**ISO 6.4.4 a-d**)

Instructions for use documentation for laboratory equipment is subject to document control procedures as defined in **MP-CGEN-002** – Document Control, including hard copies at point of use.

All personnel using equipment are subject to training and competence assessment as described in [Section 6.2](#_Personnel). Equipment used out with manufacturer specification will be subject to validation as described in **MP-CGEN-008** – Change Control, Validation and Verification.

Equipment Maintenance and Repair (**BSQR, ISO 6.4.5 a-d**)

**MP-CGEN-010** – Equipment Policy details maintenance procedures/contracts within the Department. This ensures equipment is operating within a written manufacturer’s specification, and working to a defined performance evaluated and defined by verification of the device.

For maintenance works performed by external maintenance / service engineers, **MF-CGEN-005** - Permit to Work Form to record decontamination process. **MF-CGEN-005** - Permit to Work Form must be completed **PRIOR** to maintenance / service work being performed.

Equipment Adverse Incident Reporting (**BSQR, GMP, ISO 6.4.6)**

All incidents relating to equipment are managed as defined in **MP-CGEN-005** – Risk and Incident Management Policy and **MI-CGEN-021**- Using Q-Pulse – Non-conformance module. This ensures appropriate root cause investigation is performed and corrective action implemented.

Field notices/communication from suppliers are managed using Q-Pulse non-conformance module to ensure appropriate action is taken (**MP-CGEN-011** – Management of Suppliers).

Equipment Records (**ISO 6.4.7 a-k**)

As defined in **MP-CGEN-010** – Management of Equipment Policy, the Q-Pulse system ensures:

* Equipment module – Equipment unique identifier, dates/condition, specification, location, status, preventive maintenance schedule
* Document Module – Manufacturer instructions, performance records, verification reports
* Non-conformance Module – Equipment fault/incidents

Equipment records are archived as defined in **MF-CGEN-038** - Retention Locations of QMS Documentation, Test, and Process Records and Archives.

Maintenance Records

Preventative maintenance instruction and records ensure laboratory equipment is maintained to optimum performance levels. Such Work Instructions are defined in the below:

* **For Main Analysers** – Examination Procedures include a section specific to maintenance requirements and record keeping.
* **For general laboratory equipment**, e.g. cleaning of fridges, benches, centrifuges, etc - standalone Laboratory Work Instructions/checklists serve to define maintenance tasks.

## Equipment calibration and metrological traceability (BSQR, GMP ISO 6.5)

TPS-41 provides information in relation to acceptable sources for traceability of measurement in conformance with the policy and principles of **ILAC P10:2002**, ILAC Policy on Traceability of Measurement Results **MI-CGEN-063**.

* **Calibration laboratories that are accredited to the requirements of ISO/IEC 17025,** either by UKAS or by another accreditation body that meets the requirements of this policy and is part of the ILAC Mutual Recognition Arrangement (MRA).
* Other calibration laboratories that can be shown to the satisfaction of UKAS to demonstrate competence, measurement capability and traceability with appropriate measurement uncertainty. (**Calibration laboratories that fulfil the requirements of ISO/IEC 17025 are considered to be competent**).
* Where traceability to SI units is not technically possible, traceability may be to certified reference materials or consensus standards agreed by UKAS and by the client.

**NOTE** - Calibration certificates from accredited laboratories should display the accreditation mark of the relevant accreditation body and all calibration certificates should provide a statement of uncertainty (and/or compliance if appropriate).

**NOTE** - Detailed guidance on traceability requirements for certain specific technical fields may be found in UKAS technical publications M4, accessible via **www.ukas.com**.

As stipulated by ISO the department requires a documented procedure for the calibration of equipment that directly or indirectly affects examination results. Consistent with this requirement, **MP-CGEN-010** defines the key principles.

Calibration – GMP Critical Instrumentation (BSQR)

The BSQR **MI-CGEN-064** define specific calibration requirements, for Blood Bank equipment identified as “GMP Critical” (see **MF-CGEN-006**). Requirements include the following:

|  |  |  |
| --- | --- | --- |
| **17.3.1.1** | Temperature Probes, Recorders & Chart Recorders | Critical Sensors Calibrated to Set Point +/- 0.5 deg C. |
| **17.3.1.2** | Non-Critical Sensors Calibrated to Set Point +/- 1.0 deg C. |
| **17.3.2.3** | Weighing Equipment | Calibration accuracy will depend on the precision of the balance, but the acceptable accuracy will not be more than +/- 1%. |
| **17.3.2.4** | Automated Pipettes | Calibration accuracy will depend on the precision of the device, and acceptance determined by the supplier |

## Reagents and Consumables (BSQR, GMP, ISO 6.6)

**MP-CGEN-012** – Management of Suppliers details the selection and procurement processes in the department.

**LP-CGEN-012** – Stock Management and Batch Acceptance Procedures and **LP-CBTR-006** – Stock Management Blood Bank Reagents and Consumablesdefines procedures for the reception, storage, acceptance testing, and inventory management for Laboratory Reagents, and Consumables.

**LP-CHAE-004** – Sysmex IQC Limits and XbarM Control facilitates acceptance testing of reagents associated with the Sysmex XN series. **LP-CGEN-003** - Stock Management Procedures Using the Reagent Management System (RMS) describes use of the RMS system for reagent and consumable records.

NOTE – Sysmex and Werfren IQC material is not subject to batch acceptance. This risk is assessed in **HF-CHAE-014** - Risk Assessment - Non-batch accepted Sysmex/Werfen IQC material.

Field notices/communication from suppliers are managed using Q-Pulse non-conformance module to ensure appropriate action is taken (**MP-CGEN-011** – Management of Suppliers).

## Service agreements (BSQR, ISO 6.7)

Service Level Agreement (SLA) (**ISO 6.7.1 a-c, 6.7.2**)

**MP-CGEN-013** – Policy for Service Level Agreement is used for the establishment, review, and administration of SLA’s. **MF-CGEN-017** – SLA Form – Generic and **MF-CGEN-012** – NHSGGC – POCT Checklist Form are used as a standard templates for SLAs. For tests covered by NHSGGC global SLAs **MI-CGEN-121** – Laboratory service agreement template is used.

## Externally provided products and services (BSQR, ISO 6.8)

**MP-CGEN-014** - Specimen Referral Policy (Sendaway Tests) outlines requirements for sample handling, packaging, dispatch, recording of the sending of laboratory specimens to referral laboratories for testing, and management of results and reports received from referral laboratories. Referral laboratories are audited using **QF-CGEN-068** – Referral lab audit checklist.

The Department facilitates procedure for the selection and purchasing of equipment (**MP-CGEN-010** – Equipment Policy), and reagents, calibration and quality control materials, and consumable supplies (**MP-CGEN-011** - Management of Suppliers) that have the capacity to affect the quality of the service.

# Process requirements (ISO 7.0)

## General (ISO 7.1)

Potential risk to patient care is assessed in a systematic process, as defined in the below documentation:

* **MP-CGEN-005** – Risk and Incident Management
* **MP-CGEN-029** – Clinical Risk Management
* **LP-CGEN-013** – Clinical Risk Plan
* **MF-CGEN-080** – Clinical Risk Assessment Template
* **MP-CGEN-030** – Clinical Risk Report

The above documentation describes the Departmental procedure covering pre-examination, examination and post-examination processes and is aligned with the guidance provided in BS EN ISO 22367:2020 – Application of risk management in medical laboratories.

Procedures described ensure clinical risk is assessed, reviewed periodically and reviewed in response to incidents/change. Opportunities/mechanisms to improve patient care is also described in **MP-CGEN-029** – Clinical Risk Management (see also [Section 8.5](#_Action_to_address))

## Pre-examination processes (BSQR, ISO 7.2)

General (**ISO 7.2.1**)

Departmental policy and procedures in relation to the pre-examination phase are further defined:

* **MP-CGEN-016** – Pre-examination Processes

Laboratory information for patients and users (**ISO 7.2.2**)

**MF-CGEN-022** - Service User Handbook provides information to services users and is available on the departmental website:

[Clyde Sector Haematology - NHSGGC](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/clyde-sector-haematology/)

The website also provides information on service location, transport of samples, scope of activities and the complaints process.

Request for providing laboratory examinations (**ISO 7.2.3**)

Requests for examination maybe be submitted via:

* TrackCare (electronically) generated ‘Specimen Request’
* Hard-copy, or paper equivalent (Document number)
* A separate Request Form with specimen bag is used to facilitate Blood Transfusion Requests (Document number)

Requests ***accepted*** by the Department for examination(s) shall be considered as an “agreement”, between the test requestor, and the Department. This agreement is subject to terms and conditions described in **MI-CGEN-091** – Terms and Conditions for Service Provision – Statement. Submission of a request to the laboratory indicates that consent for testing has been given. See also [Section 4.3](#_General_Requirements).

Procedures for add-on tests are defined within the associated examination procedure SOP (section 10 part VIII). Telephone procedures are further defined in **MP-CGEN-015** – Telephone procedures.

Specimen Collection and Handling (**ISO 7.2.4**)

NHSGGC Specimen Policy and, Specimen Collection (inclusive of Phlebotomy) Proceduresserve to define procedures and guidelines relating to the safe collection and handling of laboratory specimens destined for analysis by the Departments of Clinical Chemistry and Haematology (Blood Sciences).

Further information/instruction on pre-collection activities (including deviating sample action) is included in **MF-CGEN-022** – Service User Handbook

Specimen Transportation (**ISO 7.2.5**)

The General Manager, Diagnostics, NHSGGC, is nominally responsible, in association with NHSGGC Transport and Portering Managers, for the implementation and maintenance of systems for laboratory specimen transportation, inclusive of the training and management of the staff groups responsible for specimen transportation (Laboratory Staff are NOT directly responsible for Specimen Transportation).

Information for Service Users regarding specimen transportation and pan-NHSGGC distribution, inclusive of packaging requirements, is provided via **MF-CGEN-T-022** - Service User Handbook.

Specimen transport arrangements are defined in **LP-CBSC-003** – Specimen Transport Procedures. Transport audit procedures are defined in **LP-CBSC-004** – Specimen Transport Audit – Schedules and Procedures.

Nonconformity related to transport/specimen integrity is managed via Q-Pulse ensuring correct stakeholders are notified when nonconformity occurs.

[Blood and Blood Product Transport](#INDEX) - Departmental Process (**BSQR**)

In compliance with the BSQR **MI-CGEN-064** Quality Standards:

* **LI-CGEN-005** – Taxi Contract – Drivers Handbook (excerpt), serves to define instructions for the transport and distribution of blood and blood products, by Contracted Taxi Service,
* **LI-CGEN-006** – Transport and Distribution of Specimens, Blood and Blood Products by Taxi, Courier and Van, serves to define instructions for the transport and distribution of specimen, blood and blood products, by Van and Courier Services.

Sample Receipt (**BSQR, ISO 7.2.6**)

**LP-CBSC-001** – Specimen Reception Procedures – Blood Sciences defines reception procedures related to – labelling (unequivocal traceability), acceptance criteria, sample PID, pre-examination requirements and urgent sample instructions.

**NOTE** – **LP-CBTR-004** defines instruction / criteria (**BSQR**) for the acceptance and rejection for Blood Transfusion Requests and includes procedures for the reporting of those requests which have been rejected.

**NOTE** – Requirement for user notification of a result associated with a deviating samples is include in **MP-CGEN-022** - Post Examination (Post-Analytical) Processes

Authorisation is granted for specimen acceptance assessment after appropriate training (see [Section 6.2](#_Personnel)) recorded in the following documentation:

* **MF-CGEN-035** - Healthcare Support Worker (Band 2, 3 & 4) - Training Log
* **MF-CGEN-032** - Biomedical Scientist - Training Log - Haematology Laboratory
* **MF-CGEN-033** - Biomedical Scientist - Training Log - Transfusion Laboratory

## Examination processes (BSQR, GMP, ISO 7.3)

Departmental policy and procedures in relation to the examination phase are further defined in the below documents:

* **MP-CGEN-016** – Examination Processes
* **LI-CBTR-011** – Blood Bank – Examination Phase – Process Flowchart

General (**ISO 7.3.1 a-e**)

**MP-CGEN-008** – Change control, validation and verification serves as a strategy document to define change, validation and verification processes. This includes commitment to ensuring examinations are valid, maintaining critical processes and systems in a valid state.

Performance characteristics of each examination is assessed during formation of User Requirement Specification, as described in **MP-CGEN-008** – Change control, validation and verification. All documentation related to examination procedures is subject to document control procedures as described in [Section 8.3](#_Control_of_management).

All examination procedures are defined (**EP-CGEN-001** - Examination Procedure Template) and LIMS systems/middleware records the identity of staff performing significant activities.

Examinations are periodically reviewed at the Management Team Meeting and Haematology Management Team Meeting (Lines of communication - [Section 5.4](#_Structure_and_authority)).

Verification of examination methods (**ISO 7.3.2 a-f**)

Verification procedures are defined in **MP-CGEN-008** – Change control, validation and verification. A summary of the process is provided *figure 1*:



**MF-CGEN-008** – Verification form ensures performance characteristics selected for verification are aligned to clinical utility of the examination and records of personnel involved in verification. **MP-CGEN-008** – Change control, validation and verification also provides information on the extent of verification.

Training is provided to all personnel assessing verification data (**MF-CGEN-T-044** – Training Log – Senior Scientist)

All verification records are stored in Q-Pulse document module using the document number pre-fix below:

* **VD-XXX-XXX** – Verification data (results obtained)
* **VR-XXX-XXX** – Verification report (performance specification to be achieved, performance specification attainment and any action required)

Verification strategy is defined in **MF-CGEN-006** – Verification Master Plan.

Validation of examination methods (**ISO 7.3.3 a-e**)

It is departmental policy to only source examination which have been validated for use as demonstrated by presences of CE/UKCA mark (**MP-CGEN-008** – Change control, validation and verification). **MF-CGEN-010** – Performance Qualification Note (RE-verification Form) is used to ensure the valid state is maintained as described in **MF-CGEN-006** – Verification Master Plan.

Evaluation of Measurement Uncertainty (**ISO 7.3.4 a-h**)

**MP-CGEN-027** – Measurement uncertainty describes the in-house process of measurement uncertainty assessment which is aligned with guidance in ISO/TS 20914:2019 – Medical laboratories – Practical guidance for the estimation of measurement uncertainty.

Measurement uncertainty is audited/assessed annually (**AUD177-X**) and is recorded in **MI-CGEN-091** – Measurement Uncertainty Report. Measurement uncertainty information is available to the users on request (**MF-CGEN-022** - Service User Handbook).

Biological reference intervals and clinical decision limits (**ISO 7.3.5 a-d**)

As further defined in **MP-CGEN-021** – Examination Processes, reference intervals are defined as the central interval, which includes 95% of the statistical distribution of results, observed in a sample (reference sample) randomly selected from a (reference) population of reference individuals. The health status of these individuals is well defined.

Reference values for each Examination Procedure are:

* Defined on each laboratory report,
* Provided within the **MF-CGEN-022** - Service User Handbook
* Defined in individual test Examination Procedures (**EP**-XXX-XXX)
* Laboratory information documents (see below)

Reference values are reviewed by laboratory/medical team in response to document control cycle (**LI-CHAE-034** – FBC Reference Ranges, **LI-CHAE-035** - Coagulation Reference Ranges and Alarm Limits) and alteration to risk profile (**LP-CGEN-013** – Clinical Risk Plan). Activities to determine population suitability for reference ranges are recorded in **AUD244** – Reference range review (FBC/Coagulation/ESR).

Documentation of Examination Procedures (**ISO 7.3.6 a-f**)

**EP-CGEN-001** – Examination Procedure Template is to record all examination procedures, ensure consistent application of activities and validity of results.

All examination procedure documentation (instructions, forms and records) are subject to document control procedures as described in **MP-CGEN-002** - Document Control and **MP-CGEN-003** - QMS Documents & Patholological Records - Storage, Retention & Archive Policy.

Abbreviated information in documentation available at point of use (‘LI’’) clearly states the relationship to full written procedure within the LI document.

Requirement for communication of change in examination procedures to users is assessed as part of **MF-CGEN-007** – Change Control Form.

Ensuring the Validity of examination results (**ISO 7.3.7**)

General (**ISO 7.3.7.1**)

As further defined in the Departmental **MP-CGEN-017** – Policy and Procedures for Quality Assurance defines the procedure for ensuring validity in results, including detection of trends/shifts and application of statistical analyses.

Assessment of ongoing validity of examination is determined via **MF-CGEN-006** – Verification Master Plan. This details critical processes, equipment, facilities and systems, and procedures for recording when they were last verified and when re-verification (**MF-CGEN-010** – Performance Qualification Note (Re-verification Form) is due.

Internal quality control (**ISO 7.3.7.2 a-g**)

**MP-CGEN-017** – Policy and Procedures for Quality Assurance defined the internal quality control policy for the Department. This defines:

* Multilevel internal quality control is used pertinent to clinical decision
* Requirement for definition of internal quality control frequency for each examination
* Requirement for internal quality control acceptance/rejection criteria for each examination
* Application of 3rd party control material, where appropriate

Where internal quality control material is not available and alternative approach is sought. **EP-CGEN-001** – Examination Procedure Template (part 8) ensures frequency/review of internal quality control data is defined, regular and meaningful. Frequency of internal quality control is also assessed as part of risk control procedures (**MF-CGEN-080** – Clinical Risk Assessment Template).

Action required in event of internal quality control failure/appropriate corrective action is defined in **EP-CGEN-001** – Examination Procedure Template (part 8) for all examinations.

Monthly internal quality control data audit for detection trend/shift is defined in **MP-CGEN-017** – Policy and procedure for Quality Assurance. Application of X-Bar-Mean principles is defined in **LP-CHAE-004** – Sysmex IQC Limits and XbarM Control. **LF-CHAE-027** - End if day QC – Drift Control – Haematology and **LF-CHAE-028** – End of day QC – Drift Control – Coagulation is also applied, where appropriate.

**MF-CGEN-010** – Performance Qualification Note (Re-verification form) ensures continued assessment of internal quality control material as ‘fit for use’.

External quality assessment (**ISO 7.3.7.3 a-i**)

As defined in **MP-CGEN-007** – Quality Policy ([Appendix B](#_Appendix_B)) the Department shall participate in external quality assurance schemes (proficiency testing), where schemes are available, for all examinations. A register of all EQA schemes is recorded in the below documentation:

* **QF-CGEN-017** – EQA Register
* **QF-CGEN-018** – POCT EQA Reregister

Procedures for enrolment, participation and performance in EQA is defined in **LP-CGEN-004** - Procedures for the Administration of EQA, Inclusive of Analysis, Reporting, and Results Management.

Assessment of scheme suitability is performed via **QF-CGEN-059** – EQA annual Summary Form. This includes assessment of level and frequency of EQA and providers compliance with BS EN ISO 17043.

Where EQA schemes are not available a suitable alternative shall be used (**LP-CGEN-004** - Procedures for the Administration of EQA, Inclusive of Analysis, Reporting, and Results Management.)

EQA data is reviewed using **QF-CGEN-016** - EQA Results Summary Report Form (LAB STAFF) ensuring assessment against acceptability criteria defined in **LP-CGEN-004** - Procedures for the Administration of EQA, Inclusive of Analysis, Reporting, and Results Management.

‘Out with consensus’ results are managed via non-conformance procedures as defined in **MP-CGEN-005** – Incident and Risk Management. Assessment of release of non-conforming work and requirement for appropriate remedial action is prompted via standard non-conformance template, as described in **MI-CGEN-021** – Using Q-Pulse – Non-conformance module.

Comparability of examination results (**7.3.7.4 a-e**)

**LP-CGEN-010** – Comparability Procedures for Examination Results describes cross-site comparability studies, used to identify:

* The correlation of results, where different testing systems are used, i.e. comparison of results from different analyser systems (e.g. FBC using XS Analyser versus XT Analyser System).
* The correlation of results using identical testing systems, i.e. where different hospital sites use the same equipment.

As further defined in **LP-CGEN-010** – Comparability Procedures for Examination Results, the Department operates systems to document, record and, as appropriate, expeditiously act upon results from the comparisons performed.

## Post-examination processes (ISO 7.4)

Departmental policy and procedures in relation post examination phase is detailed to in **MP-CGEN-022** - Post-Examination Processes. Procedures for the review and authorisation of laboratory test results is defined in Examination Procedures, with instructions and guidelines to include:

* Results Validation / Authorisation and Checks,
* Reference / Normal / Therapeutic Result Ranges,
* Alarm Limits (specific “trigger” values, in relation to the analyte / test),
* Add on Tests – When, Why and What Tests,
* Interpretation and Clinical Indications of Results,
* Procedure for Dealing with Abnormal Results (to senior BMS and or Medical Staff),
* Telephoning of Results – When, How and to Whom.

Reporting of results (**ISO 7.4.1**)

General (**ISO 7.4.1.1 a-c**)

Results are reported (both electronic and hard copy) as described in **MP-CGEN-022** – Post Examination Procedures, including guidance on delayed report procedure. All documentation associated with reports are stored as described in **MF-CGEN-038** - Retention Locations of QMS Documentation, Test, and Process Records and Archives.

Results review and release (**ISO 7.4.1.2**)

For the department, examination results are authorised principally by trained, qualified and competent Biomedical Scientist Staff, and also, by trained Haematology Medical Staff (see [Section 6.2](#_Personnel))

Reporting procedures for each examination are defined via **EP-CGEN-001**- Examination Template (part 11).

Critical result reports (**ISO 7.4.1.3 a-c**)

Critical result procedure is defined for each examination via **EP-CGEN-001** – Examination Template (Section 10, part ‘X’). Telephone procedures related to critical result transmission are defined in **LP-CGEN-005** – Telephone Procedures. Further information on critical result transmission is detailed in **LI-CGNE-015** – Telephoning Abnormal Results

Special considerations for results (**ISO 7.4.1.4 a-e**)

Simplified results are communicated to the user in specific situations as defined in **MF-CGEN-022** – Service User Handbook. Simplified results are always followed by a full report as defined in **MP-CGEN-022** – Post Examination Processes.

Departmental procedures relating to the telephoning of preliminary results and the logging of calls, are defined in **LP-CGEN-005** – Telephone Procedures.

Automated selection, review, release and reporting of results (**ISO 7.4.1.5 a-d**)

Where test results are automatically reported, e.g. electronic report validations, Laboratory Procedures, facilitated as an adjunct to the appropriate Examination Procedure, serve to define parameters, and procedural instructions specific to electronic validation and reporting of the test result.

An example in this regard would be the authorisation of a FBC, using the Sysmex Extended Processing Unit (EPU), where procedures specific to use of the EPU are prepared as a standalone procedure.

Requirements for reports (**ISO 7.4.1.6 a-m**)

Consistent with regulatory requirements, printed laboratory reports (departmental report forms) include the following information:

* The name of the department,
* The unequivocal identity of the patient,
* The requestor and / or the address for delivery,
* The type of specimen, and the date and time of collection,
* Time and date of report,
* Results, including reasons if no examination is performed,
* Reference intervals as appropriate,
* Interpretative comments as appropriate,
* Highlighting of abnormal results, and/or, inclusion of critical limits,
* Status of report as appropriate e.g. copy, interim or supplementary,
* The identification (where possible) of the person(s) verifying & authorising results.

Further information on report access/content is provided in **MP-CGEN-022** – Post Examination Procedures.

Additional information for reports (**ISO 7.4.1.7 a-d**)

Appropriate interpretive comments are recorded on reports as defined in the associated examination SOP e.g. **EP-CHAE-001** - Blood Film Preparation, Staining and Reporting, Part 9 – Method/Procedure.

Departmental reports (on receipt of referred test results) include the following information:

* The identity of the referral laboratory,
* All results issued by the referral laboratory,
* All interpretative comments provided by the referral laboratory.

The Department, as further defined in **MP-CGEN-022** –Post Examination Processes, chooses not to include the UKAS accreditation symbol on the laboratory hard copy and electronic reports but to include a reference to UKAS accreditation on the haematology, coagulation and bone marrow reports using the wording:

**‘Clyde Haematology labs are a UKAS accredited medical lab (No 8046) for all tests except GFST and SickleScan.’**

Blood transfusion reports make no mention of UKAS accreditation. Users are informed of our accreditation status by including a link to the UKAS Schedule of Accreditation on the laboratory website and in the service users’ handbook.

Amendments to reported results (**ISO 7.4.1.8 a-e**)

Laboratory data held by the departmental Computer (LIMS) is protected against ***unauthorised revision*** via a password access system. However, the password related hierarchy of the LIMS functions to allow designated staff access to the data for ***revision purposes***.

The department operates a systematic process (**MP-CGEN-022** – Post –examination Processes) 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, is conveyed to appropriate clinical staff.

Post-examination handling of samples (**ISO 7.4.4**)

**MP-CGEN-003** - QMS Documents & Patholological Records - Storage, Retention & Archive Policy serves to define requirements, and procedural instructions for staff for the retention of clinical material, including their release to third parties (e.g. the Police).

In addition to the above, specimen disposal procedures are further defined in the **HP-CGEN-001** - Health & Safety Code of Practice, in **HP-CGEN-002** - Clinical Waste Procedures], and in NHSGGC Clinical Waste Procedures – [Policies, Guidance Documents and Forms - NHSGGC](https://www.nhsggc.scot/staff-recruitment/hrconnect/safety-health-and-wellbeing/policies-guidance-documents-and-forms/).

[**MP-CGEN-004**](file://C:\Users\walkegr116\AppData\Local\Temp\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Graham\AppData\Local\Microsoft\Windows\QPULSE4\QMS%20DOCUMENTATION\ACTIVE%20DOCUMENTS\MAP-ALL-ALL-002.ClinMatDocRetention.doc) - The Retention and Storage and Control Of Clinical Material indicates that information relating to the control of clinical material is detailed in individual Examination Procedure documents, with details inclusive of: identification, collection, indexing, accessing, filing, storage times (including legislated minimum retention times) and disposal of Clinical Material.

## Non-conforming work (BSQR, ISO 7.5)

Activities or examination results which do not conform to the Departmental procedures, quality specifications or user requirements are managed via Q-Pulse Non-conformance modules as described in **MP-CGEN-005** – Risk and Incidents Management Policy and **MI-CGEN-021** – Using Q-Pulse Non-conformance module. The Department has established process of monitoring of amended report release via monthly pre-examination audit (**AUD164-X**). All amended reports are recorded in Q-Pulse non-conformance module and appropriate root cause analysis performed (**MP-CGEN-022** – Post-examination Processes).

The above documentation ensures:

* Responsibilities and authorities of nonconforming work are specified
* Immediate (containment) and long term (corrective) actions are specified (with requirement to assess risk)
* Halting/resumption of examination authorities and responsibilities
* Assessment of release of non-conforming work and need for clinical input as part of immediate actions (containment)

Investigation of nonconforming work is supported by **LI-CGEN-020** – Root Cause analysis – Investigation Procedures

Corrective action is applied with consideration to risk profile of the examination/process (**MP-CGEN-029** – Clinical Risk Management).

Departmental standard non-conformance template is utilised to ensure the above steps occur, as defined in **MP-CGEN-005** – Risk and Incident Management Policy and **MI-CGEN-021** – Using Q-Pulse – Non-conformance Module.

See also [Section 8.7](#_Nonconformities_and_corrective).

## Control of data and information management (BSQR, ISO 7.6)

General (**ISO 7.6.1**)

To facilitate access to laboratory data and information, consistent with the needs and requirements of the service user – see [Section 4.3](#_General_Requirements).

In addition, the department is required to facilitate procedures to assure compliance with Data Security and Patient Confidentiality – see [Section 4.2](#_General_Requirements).

Authorities and responsibilities from information management (**ISO 7.6.2**)

The authorities and responsibilities of personnel who use the Laboratory Information System (LIMS) is defined based on role. Definitions include:

1. Access to patient data and information;
2. The entry of patient data and examination results;
3. Those staff with responsibilities to change patient data or examination results;
4. Those staff with the authority to validate and report (release) examination results and reports are limited to HCPC registered Biomedical Scientists and Medical staff.

Information management systems (**ISO 7.6.3 a-e**)

Telepath system is managed by NHSGGC eHealth and defined in operational agreement **SC-CGEN-003** - OLA - NHSGGC IT Operational Agreement - Telepath LIMS. Use of Telepath system is defined in the below documentation:

* **MP-CGEN-031** - Policy And Procedures For The Management Of It Systems, Electronic Data And Information
* **LP-CHAE-003** - LIMS Data and Order Entry, and PID Procedures - Blood Sciences Laboratory
* **LP-CBTR-005** - LIMS Data and Order Entry and PID Procedures - Blood Bank Laboratory

Additional information management systems managed via Managed Service Contract (**MP-CGEN-010** – Equipment Policy), with instructional information contained in the appropriate examination or laboratory procedure.

Changes to information management systems are subject to change control procedures as described in **MP-CGEN-008** – Change control, validation and verification (e.g. **LF-BTR-045** – Re-verification post upgrade report).

Downtime plans and offsite management (**ISO 7.6.4, ISO 7.6.5**)

Defined action for information system downtime are contained in **LP-CGEN-011** - Procedures in the Event of Essential Services and or Laboratory Systems Failure. Telepath system is managed by NHSGGC eHealth and defined in operational agreement **SC-CGEN-003** - OLA - NHSGGC IT Operational Agreement - Telepath LIMS. Additional information management systems managed via Managed Service Contract (**MP-CGEN-010** – Equipment Policy).

## Complaints (ISO 7.7)

**MP-CGEN-006** - Complaints and NHSGGC Complaints procedures, seeks to ensure that complaints are handled thoroughly without delay, with the aim of satisfying the complainant whilst being fair and open with all those involved. **MP-CGEN-006** – Complaints Policy is available to service user on the Department [website](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/clyde-sector-haematology/).

## Continuity and emergency preparedness planning (ISO 7.8)

Contingency planning procedures are defined in the below documentation:

* **LP-CGEN-011** - Procedures in the Event of Essential Services and or Laboratory Systems Failure
* **MP-CGEN-028** - GGC Haematology Business Continuity Plan

# Management system requirements (BSQR, ISO 8.0)

## General requirements (ISO 8.1.1)

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))

Commitment to fulfilment of management system requirements is defined in **MP-CGEN-007** – Quality Policy ([Appendix B](#_Appendix_B)). This is available to service users via the Departmental [website](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/clyde-sector-haematology/).

Personnel are made aware of the requirement and function of the quality management system via induction procedures, using the training events listed below:

* **MF-CGEN-T-024** – New Staff Orientation and Induction Form
* **MI**-**CGEN-093** – Quality Management System – An introduction
* **MF-CGEN-T-001** – Training Log – Q-Pulse User Training

Updates to the quality management system are communicated via communication lines defined in [Section 5.4](#_Structure_and_authority) and document control procedures ([Section 8.2](#_Management_system_documentation)).

## Management system documentation (ISO 8.2)

General (**ISO 8.2.1**)

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

1. The quality policy or makes reference to it;
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.

Competency and quality (**ISO 8.2.2**)

Competence and quality are committed to via **MP-CGEN-007** – Quality Policy ([Appendix B](#_Appendix_B)).

Evidence of commitment (**ISO 8.2.3**)

Evidence to commitment to development of implementation of the management system is generated via:

* **QF-CGEN-015** – Quality Objectives and Plans Report Form
* **LP-CGEN-013** – Clinical Risk Plan
* **MP-CGEN-005** – Risk and Incident Management
* **MP-CGEN-020** – Personnel Management – Policy and Procedures
* **MP-CGEN-019** – Training Policy

Documentation (**ISO 8.2.4**)

All documentation related to fulfilment of the requirement of BS EN ISO 15189:2022 are in the included and managed using defined document control procedures (**MP-CGEN-002** – Document Control).

Personnel access (**ISO 8.2.5**)

Documentation necessary for performance of laboratory examinations, and consultation, are readily available to relevant staff both inside and out with the Department. Personnel access to quality management documentation and information is managed using **MF-CGEN-024** – New Staff Orientation and Induction Form. QMS documentation is subject to strict management control, and subject to defined review and amendment, as appropriate. The QMS document management system (Q-Pulse, Ideagen Ltd) – software functionality and aspects of electronic document control are defined in **MI-CGEN-002** – Using Q-Pulse – Document Module

## Control of management system documents (ISO 8.3)

As defined in **MP-CGEN-002** - Document Control policies and procedures are controlled and effectively implemented to ensure that Departmental User requirements are satisfied. This documentation serves to ensure:

* QMS documentation is approved for use by authorised personnel, prior to use,
* QMS documents are uniquely identified, paginated, and have traceability to the date of issue (active date), revision version, version history, and staff responsible for authorization (activation),
* There is a readily accessible Master List (‘Active Register) that prevents the use of invalid, or obsolete, documents,
* 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 is restricted to authorised staff (Q-Pulse Password Control)

Hardcopy documentation available in the department is audited via monthly housekeeping audits (**LF-CGEN-019** – Housekeeping audit checklist – **AUD175**) and displayed documentation is audited quarterly (**MP-CGEN-017** – Procedures for Quality Assurance - **AUD178**).

## Control of records (ISO 8.4)

The Department operates a procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records as defined in the below documentation:

* **MP-CGEN-003** - QMS Documents & Patholological Records - Storage, Retention & Archive Policy
* **MI-CGEN-042** - The Retention & Storage of Pathological Records & Archives (IBMS and RCPath Guidelines)
* **MI-CGEN-041** – NHS Scotland - Records Management

This documentation ensures/defines that:

* Records can be in any form or type of medium providing they are readily accessible and protected from unauthorised alterations.
* The date and, where relevant, time of amendments to records shall be captured along with the identity of personnel making the amendments
* The laboratory shall define the time period that various records pertaining to the QMS, including pre-examination, examination and post-examination processes, are to be retained. The length of time that records are retained may vary; however, reported results shall be retrievable for as long as medically relevant or as required by regulation.
* Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain records for much longer periods than for other records.
* Facilities shall provide a suitable environment for storage of records to prevent damage, deterioration, loss or unauthorised access
* For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location

## Action to address risks and opportunities for improvement (ISO 8.5)

Identification of risks and opportunities for improvement (**ISO 8.5.1**)

The Department applies systematic approach to risk management as defined in **MP-CGEN-005** – Risk and Incident Management. Procedures are further defined in the below documentation:

* **HP-CGEN-001** – Health and Safety Code of Conduct
* **MP-CGEN-029** – Clinical Risk Management
* **LP-CGEN-013** – Clinical Risk plan

Where appropriate, risk management processes has been aligned to guidance provided by [NHSGGC policies and procedures](https://www.nhsggc.scot/staff-recruitment/hrconnect/safety-health-and-wellbeing/policies-guidance-documents-and-forms/) and BS EN ISO 22367:2020 - ISO 22367:2020 - Application of risk management to medical laboratories.

**MP-CGEN-017** – Policy and Procedures for Quality Assurance defines a series of Quality Indicators / Performance Assessment Tools (inclusive of details relating to the methodology of assessment and the duration of measurement). Indicators cover pre-examination, examination, and post-examination phases and allow for assessment of service Quality and Improvement.

Acting on risk and opportunities for improvement (**ISO 8.5.2**)

Action taken to reduce risk to patients are recorded using **MF-CGEN-080** – Clinical Risk Assessment Template. Action taken to assess risk to personnel is recorded in the associated documentation for the process/activity. Action is taken on identified risks based on risk acceptance criteria as defined in **MP-CGEN-029** – Clinical Risk Management and **HP-CGEN-001** – Health and Safety Code of Conduct.

Identification of risk level determined using the above procedures is utilised to drive improvement in the Department.

## Improvement (ISO 8.6)

Continual improvement (**ISO 8.6.1**)

Processes present to ensure continual improvement are defined below:

* Formation and review of annual quality objectives (**QF-CGEN-015** - Quality Objectives and Plans Report Form, **MF-CGEN-068** - Management Meeting Agenda Form, **MF-CGEN-079** - Annual Management Review Agenda Template)
* Routine assessment of key performance indicators (**MP-CGEN-017** – Policy and Procedure for Quality Assurance) for the below metrics:
	+ Complaints
	+ Full blood count turnaround time
	+ D-Dimer turnaround time
	+ Cross match turnaround time
	+ Staff absence and development
	+ Amended reports
	+ SHOT reporting
	+ Non-conformance trending (**MF-CGEN-072** – Quality and training Report)
* Application and assessment of risk processes as defined in **LP-CGEN-013** – Clinical Risk Plan
* Pre-examination error audit (**AUD164**)

Improvement identified via routine assessment of data generated from the sources above are logged as a ‘Preventive action’ using Q-Pulse non-conformance module. These are subject to the procedures defined in **MP-CGEN-005** – Risk and Incident Management and **MI-CGEN-021** – Using Q-Pulse – Non-conformance module.

Further information is available in **MP-CGEN-017** – Policy and Procedures for Quality Assurance.

Laboratory patients, user and personnel feedback (**ISO 8.6.2**)

Feedback is used to improve management system, laboratory activities and service quality. Feedback mechanisms present in the Department are described below:

|  |  |
| --- | --- |
| **Demographic** | **Mechanism** |
| User/Patients  | * **MF-CGEN-086** - NHSGGC Clyde Haematology and Blood Transfusion user feedback form (published on website and in MF-CGEN-022 – Service user handbook).
* **MP-CGEN-006** – Complaints policy (available on Departmental [website](https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/clyde-sector-haematology/))
* User survey (electronic questionnaires sent to users)
* Informal feedback from a user interaction (recorded using ‘User interaction’ wizard in Q-Pulse non-conformance module)
* User meetings as described in lines of communication ([Section 5.4](#_Structure_and_authority))
 |
| Staff | * ‘Improvement ideas’ function in Q-pulse for suggestion of quality improvement
* **LF-CGEN-022** - Anonymous Staff Suggestion Form (Published to staff SharePoint Hub)
* NHSGGC ‘[iMatter’ survey](https://www.nhsggc.scot/staff-recruitment/hrconnect/imatter/)
* Personnel meetings as described in lines of communication ([Section 5.4](#_Structure_and_authority))
 |

Feedback is routinely discussed at Departmental Management, Senior and General Staff Meetings, as appropriate. Summary reports relating to user requirements, and associated performance objectives and improvements, form a standing agenda of the Departmental Annual Management Review Meeting.

## Nonconformities and corrective actions (ISO 8.7)

All nonconformity is logged using the non-conformance module in Q-Pulse. Standard actions involved/timeframes are defined below:

|  |
| --- |
|   **within 7 days (Stage Owner)** |
| What immediate action has been taken? Assessment of nonconforming work release. Describe what has been done to mitigate the effect of the incident. If the issue has an impact on any results these should be stopped with no report issued (or recalled if appropriate) until an investigation is complete. Trigger incident escalation processes if required (**MP-CGEN-005**). |
|  **within 7 days (Stage Owner)** |
| Why did it happen? Ask ‘why’ (x5) and consider how it can be corrected. Procedure wasn’t followed, why? Is it related to training, why? Training documents are not in place, etc |
|   **within 7 days (Stage Owner)** |
| Having identified possible causes, evaluate the need for corrective action. How can it be fixed?This may include the head of laboratory authorizing procedures to be resumed e.g. copy of report sent, QC records updated. As example above, implement training and competency check. |
|   **within 21 days (Quality Manager Only)** |
| All the above will be considered and checked to see if the steps are adequately recorded and clinical risk assessment review triggered, if appropriate. Assessment of nonconformity impact on clinical risk assessment/improvement opportunity confirmed. If OK the record will be closed. If further info is needed the steps may be re-opened. |

Non-conformance training is delivered using **MI-CGEN-T-125** - Non-conformance training. Further information is available in **MP-CGEN-005** – Risk and Incident Management on additional reporting systems (e.g. DATIX, SHOT/SABRE and UKAS). Root cause analysis procedures are further defined in **MP-CGEN-020** – Root Cause Analysis – Investigation Procedures.

Technical information of logging nonconformity is contained in **MI-CGEN-021** – Using Q-Pulse – Non-conformance module.

## Evaluations (ISO 8.8)

General (**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 users are met.

Quality indicators (**ISO 8.8.2**)

In addition to KPIs described in [Section 8.6](#_Improvement_(ISO_8.6)), **MP-CGEN-017** – Policy and Procedures for Quality Assurance defines a series of Quality Indicators / Performance Assessment Tools. These are evaluated as below:

|  |  |  |
| --- | --- | --- |
| **Activity** | **Methodology of Assessment** | **Duration of Measurement** |
| Patient identification (pre-examination)  | Routine ProcessScheduled Horizontal AuditScheduled Vertical Audit | ContinuousAudit shall incorporate a pre-specified number of requests |
| Test order accuracy (pre- examination) |
| Adequacy of specimen information (pre- examination) |
| Accuracy of PID (pre- examination) |
| Accuracy of Point of Care Testing (examination) | Routine Process – includes IQC & EQAScheduled Horizontal AuditScheduled Vertical Audit | ContinuousAudit shall incorporate a pre-specified number of analyses |
| Accuracy of Laboratory Analytical Testing (examination) | Routine Process – includes IQC & EQA | Continuous |
| Clinical Advice Availability, including Timeliness of Responding to Requests for Clinical Advice, and, availability of clinical advice at multidisciplinary meetings (infrastructure) | Routine process – Professional liaison & Complaints PolicyUser Satisfaction Survey | ContinuousSurvey undertaken biennially |
| Staff Appraisal - Consultant, Clinical Staff, Clinical Scientific Staff and eKSF, PDP & CPD (infrastructure)  | Routine process | ContinuousAnnual Audit |
| Critical value reporting & communication (post- examination) | Routine ProcessScheduled Horizontal AuditScheduled Vertical Audit | ContinuousAudit shall incorporate a pre-specified number of reports, and report types |
| Results reporting (post- examination) | Routine ProcessScheduled Horizontal AuditScheduled Vertical Audit | ContinuousAudit shall incorporate a pre-specified number of reports, and report types |
| Accuracy of Standard Operating Procedures (Quality Management System (infrastructure)) | Scheduled Horizontal AuditScheduled Vertical AuditScheduled Examination Audit | Audit is scheduled to incorporate all standard operating procedures |
| Compliance of Standard operating procedures with British Haematology Society (BSH) Guidelines  | Gap analysis using MF-CGEN-090 - Guideline gap analysis tool | Initial release of guidelines, in response to updated guidelines.  |
| Health & Safety & Environmental Monitoring | Scheduled Horizontal Audit | A number of Audits are utilised to cover the diversity of Laboratories Health & Safety |
| Internal Quality Control (infrastructure) | Routine ProcessScheduled Horizontal Audit | ContinuousHorizontal Audit is scheduled to include all IQC performed |
| External Quality Assurance (infrastructure) | Routine Process | Continuous |
| Turnaround time (infrastructure) | Service indicators – FBC, DD, Crossmatch, Amended reports | Monthly Horizontal Audit and trending at Management Meeting |
| Service User Satisfaction (infrastructure) | Scheduled Horizontal Audit (focused survey), General User Survey Questionnaires, Open Liaison Meetings, and general communications | Service User Audit is scheduled to be undertaken no less than every two years. |
| Service User Complaints (infrastructure) | Routine Process | Continuous |
| Staff Satisfaction (infrastructure) | Scheduled Horizontal AuditOrganisational Audit (NHSGG&C, & National Staff Survey Schemes) | Audit involves all Departmental staff |
| Staff Complaints (infrastructure) | Routine Process | Continuous |
| Staff Training & Competency (infrastructure) | Scheduled Horizontal Audit | Audit shall incorporate a pre-specified number of staff |
| Blood usage and wastage (post- examination) | Horizontal Audit | Monthly |
| Blood Traceability (post- examination) | Horizontal Audit | Monthly |

|  |  |  |
| --- | --- | --- |
| **Activity** | **Methodology of Assessment** | **Duration of Measurement** |
| NHS Never Event – Transfusion of ABO-incompatible blood component | Routine Process - Incident Management | Continuous |
| Near Miss Event – Sampling (mis-identification, labelling, phlebotomy |
| SHOT Reporting |
| BSQR Requirements | * Annual Hospital Compliance Report
* MHRA Inspection / Audit
* Internal Audit
 | ContinuousAnnual Reporting |
| Practitioner / Staff Competence | * Mandatory Training Program
* Staff Training Program
* Competency Assessment Program
* TAAP – Blood Transport
 | Continuous |

Internal Audits (**ISO 8.8.3**)

Audit procedures are defined in **MP-CGEN-017** – Policy and Procedures for Quality Assurance. The department operates a cyclical internal audit schedule running over a 4 year period encompassing all examinations performed.

In addition to cyclical internal audit the Department operates a risk based audit schedule allowing identification of nonconformity in high risk areas. Scheduling of a risk based audit is trigged by assessment of a number of factors including:

* Non-conformance trending
* Personnel feedback
* Change control (post implementation review)
* External audit

Audit calendars are organised using Q-Pulse audit module as below:

Clyde Haematology Audit Schedule

External Calendar

Performance Calendar

Internal Calendar

H+S Calendar

* User survey
* Staff Satisfaction
* TAT
* BT Tags
* Risk Based
* Housekeeping
* BSQR
* Vertical
* Horizontal
* Examination
* Competence
* Fire
* Waste
* Workplace
* UKAS
* MHRA
* HSE

Audit of the QMS includes pre-examination, examination and post-examination phase. Types of internal audit utilised include:

|  |  |
| --- | --- |
| **Type** | **Function/Guidance** |
| Horizontal audit | * Detailed check of a particular component part of the QMS.
* **QF-CGEN-011** – Horizontal audit checklist
* Ad-hoc electronic checklist (**MI-CGEN-020** – Using Q-Pulse – Audit Module)
 |
| Vertical Audit | * Audit of a sample through all phases against full BS EN ISO 15189:2022 standards
* **QF-CGEN-032** – Vertical audit checklist
* Ad-hoc electronic checklist (**MI-CGEN-020** – Using Q-Pulse – Audit Module)
 |
| Examination audit | * Examination Procedure or Laboratory Work Instruction is witnessed as it is performed to determine operator compliance.
* **QF-CGEN-032** – Vertical audit checklist
* Ad-hoc electronic checklist (**MI-CGEN-020** – Using Q-Pulse – Audit Module)
 |

External Audit or Review by External Organisations

Details of the MHRA Inspection process are defined - [The MHRA Hospital Blood Bank Inspection Process (transfusionguidelines.org)](https://www.transfusionguidelines.org/document-library/documents/the-mhra-hospital-blood-bank-inspection-process). Further information is available in **MP-CGEN-018** - Management of the Blood Safety & Quality Regulations (BSQR).

Full details of the UKAS assessment process, the requirements of ISO 15189:2022, and scheme participants, can be accessed via [http://www.ukas.com](http://www.ukas.com/). Further information is available in **MI-CGEN-086** - UKAS Publication - GEN 1 - UKAS Policy - General Principles for the Assessment of Conformity Assessment Bodies by UKAS

## Management reviews (ISO 8.9)

Departmental Management Team coordinates formal Annual Management Review. This meeting is conducted using a defined protocol MP-CGEN-015 – Annual Management Review Procedure, and standing agenda MF-CGEN-079 – Annual Management review Agenda Template.

#

# Appendix A – Laboratory Director Job Description

NHS Greater Glasgow and Clyde require a consultant haematologist to professionally direct each Haematology/Blood transfusion Laboratory. Within the Clyde Sector this is the Role of the Clyde Sector Laboratory Director who is professionally responsible and managerially accountable for the laboratories at Royal Alexandra Hospital, Inverclyde Royal Hospital and Vale of Leven Hospital. There are nominated consultants for Blood Transfusion and thrombosis who assist the Laboratory Director. The Laboratory Director in turn is professionally responsible and managerially accountable to the Head of Service and the Haematology Management Team.

The Duties, and delegated duties, of the Laboratory Director are outlined under ISO 5.2. These are fully documented within the Clyde Sector Quality manual but the Laboratory Director duties include;

1. Provide effective leadership of the Regional Services run medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.
2. Relate and function effectively with applicable accreditation and regulatory agencies, appropriate administrative officials, the healthcare community, the patient population served, and providers of formal agreements, when required.
3. 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.
4. Serve as a contributing member of the medical staff for these facilities served, if applicable and appropriate.
5. Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and the interpretation of examination results.
6. Define, implement and monitor standards of performance and quality improvement of the medical laboratory service and services.
7. Monitor with the lab management team all work performed in the Laboratory to determine that clinically relevant information is being generated.
8. Address any complaint, request or suggestion from staff and/or users of medical laboratory services.
9. 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.
10. Plan and direct research and development, where appropriate.
11. Roles and Responsibilities of the Laboratory Director and the Laboratory Management Team
12. Outlined below are the Lab director duties, or delegated duties as appropriate, under**:**

|  |  |  |
| --- | --- | --- |
| **Duty** | **Responsibility** | **Comment** |
| a) 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 and Lab Management Team | Through Haematology Management Team (HMT) and Managed Service Contract (MSC) budget meetings. |
| b) Relate and function effectively with applicable accreditation and regulatory agencies, appropriate administrative officials, the healthcare community, the patient population served, and providers of formal agreements, when required. | Laboratory Director, TSM and Sector Lab Manager | Senior lab staff will deal directly with UKAS and MHRA. Lab issues user surveys, newsletters and has SLA’s with all outside service users. |
| 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 | Medical staff – Regional Management TeamLab staff – Diagnostic Management Team | Training and education records kept for all staff. |
| d) Ensure the implementation of the quality policy. | TSM, Sector Lab Manager and Quality Manager | Controlled document in QMS. |
| e) Implement a safe laboratory environment in compliance with good practice and applicable requirements. | TSM and Sector Lab Manager | H&S committee meet every 3 months and is a standing item on monthly staff meetings. |
| f) Serve as a contributing member of the medical staff for these facilities served, if applicable and appropriate. | Laboratory Director |  |
| g) Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results. | All Clyde Consultant Medical Staff | A 24/7 on call medical staff rota operates for Clyde. |
| h) Select and monitor laboratory suppliers | Diagnostic Management Team | Controlled by the Managed Service Contract with Abbott Healthcare. |
| i) Select referral laboratories and monitor the quality of their service. | TSM, Sector Lab Manager and Quality Manager | All referral labs are evaluated using MF-CGEN-017. |
| j) Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations. | TSM, Sector Lab Manager and Quality Manager | All staff complete mandatory training, NEQAS, CPD, attend scientific meetings and lunchtime educational presentations. |
| k) Define, implement and monitor standards of performance and quality improvement of the medical laboratory service and services. | Laboratory Director, TSM and Lab Management Team | Defined through quality manual and monitored via balanced scorecard monthly at HMT. |
| l) Monitor all work performed in the laboratory to determine that clinically relevant information is being generated. | Laboratory Director, TSM and Sector Lab Manager | Use audit module in QMS, incident reporting tools DATIX/HTT and weekly consultant meetings. |
| m) Address any complaint, request or suggestion from staff and/or users of laboratory services. | Laboratory Director, TSM and Sector Lab Management Team | Managed via QMS system, staff meetings and HMT. |
| n) 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 and Sector Lab Manager | Contingency Plans in QMS (LP-CGEN-011) and GG&C policies within StaffNet. |
| o) Plan and direct research and development, where appropriate. | Laboratory Director, TSM and Sector Lab Manager |  |
| p) Application of risk management to all laboratory activities | TSM, Sector Manager and Quality, Training and PoCT Manager | Primarily role of Sector Manager and Quality, Training and PoCT Manager. |

# Appendix B – MP-CGEN-007 – Quality policy

