|  |
| --- |
| Quality MANUAL |
| This Document together with Policy and Procedure documents to which it refers, serves to define the Quality Management System of the Department of Haematology, Clyde Sector, NHS Greater Glasgow & Clyde. The document has been compiled to meet with requirements of the Blood Safety and Quality Regulations 2005 (“the principal Regulations”), and subsequent amendments; UKAS (ISO: 15189); and other National and International Standards, as appropriate. All policies and procedures specified herein are mandatory within the Department of Haematology, Clyde Sector, NHSGGC. |
| **Scope & Purpose of Document** |
| This Quality Manual, together with Policy and Procedure documents to which it refers, serves to define the Quality Management System of the Department of Haematology, Clyde Sector, NHSGGC. The document has been compiled to meet with requirements of UKAS, MHRA, GMP, and other appropriate national and international quality standards. 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.Additional Scope & Purpose is defined in the text. |
| **Document Version Changes** |
| Version 10 is amended to Version 11 to update Medical Staff listing, and to reference MI-CGEN-086 (UKAS GEN1) and remove referencing to TPS51 – see Section 13.7.2. |
| **Document References** |
| * ISO 15189: 2012 – Medical Laboratories – Requirements for Quality & Competence
* ISO 9001(E) - Quality management systems - Requirements
* ISO 17025: 2005 - General requirements for the competence of testing and calibration laboratories
* ISO 9000:2005 - Quality management systems - Fundamentals and vocabulary
* ISO 22870:2006 - Point of Care Testing (POCT) – 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
* GMP - Good Manufacturing (Laboratory) Practice
* UKAS Publications - TPS 41, 47, 51, 53 and 57
* UKAS Publications – LABS: 1, 3, 5, 11, 12, 14, 15 and 36
 |
| **Related Documents** |
| 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. |

Index:

[1.0 Introduction 5](#_Toc2081403)

[2.0 Organisation & Management Responsibility (ISO 4.1) 6](#_Toc2081409)

[3.0 Quality Management System (ISO 4.2) 15](#_Toc2081437)

[4.0 Document Control (ISO 4.3) 15](#_Toc2081441)

[5.0 Examination by Referral Laboratories (BSQR, ISO 4.5) 16](#_Toc2081444)

[6.0 External Services and Supplies (ISO 4.6, 5.3) 17](#_Toc2081446)

[7.0 Advisory Services (ISO 4.7) 17](#_Toc2081447)

[8.0 Resolution of Complaints (ISO 4.8) 17](#_Toc2081448)

[9.0 Identification & Control of Non-Conformity (ISO 4.9) 18](#_Toc2081449)

[10.0 Corrective and Preventative Action (CAPA) (4.10 and 4.11) 18](#_Toc2081452)

[11.0 Continual Improvement Framework (ISO 4.12, 4.14.7) 18](#_Toc2081453)

[12.0 Control of Records (ISO 4.13) 18](#_Toc2081454)

[13.0 Evaluation, Quality Assurance and Audit (ISO 4.14) 19](#_Toc2081456)

[14.0 Management Review (ISO 4.1.2.1, ISO 4.15) 23](#_Toc2081472)

[15.0 TECHNICAL REQUIREMENTS (ISO 5.1) 23](#_Toc2081473)

[16.0 Accommodation & Environmental Conditions (ISO 5.2) 25](#_Toc2081485)

[17.0 Laboratory Equipment, Reagents & Consumables (ISO 5.3) 27](#_Toc2081496)

[18.0 PRE-EXAMINATION PROCESS (ISO 5.4) 31](#_Toc2081497)

[19.0 Examination Processes (ISO 5.5) 33](#_Toc2081498)

[20.0 Assuring the Quality of Examinations (ISO 5.6) 34](#_Toc2081499)

[21.0 Post- Examination Processes (ISO 5.7, 5.8, 5.9) 35](#_Toc2081500)

[22.0 Management of Data and Information (BSQR, ISO 5.10) 40](#_Toc2081501)

# 1.0 Introduction

## 1.1 Scope and Purpose

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.

The document has been compiled principally to meet with requirements of the United Kingdom Accreditation Service (UKAS), The Blood Safety & Quality Regulations (as formally inspected by the Medicines & Healthcare Regulatory Authority (MHRA)), and Good Manufacturing (Laboratory) Practice (GMP), and, other relevant National and International Quality Standards.

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

The Quality Manual aims to fulfil two principle functions:

1. It describes the Quality Management System for the benefit of Departmental Staff,
2. It provides insight into the organisation for interested parties outside.

## UKAS Accreditation (BN ISO: 15189 (2012))

The BN ISO: 15189 (2012) International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies requirements for competence and quality that are particular to medical laboratories.

## Blood Safety & Quality Regulations

The Blood Safety and Quality (Amendment) Regulations 2007 No. 64 which came into force on 1st April 2007. These Regulations further amend the Blood Safety and Quality Regulations 2005,“the principal Regulations”, and implement:- Commission Directive 2005/61/EC, and, Commission Directive 2005/62/EC

## GMP

As yet, there are no published Good Practice Guidelines for Blood Establishments and Blood Banks, the equivalent of the GMP Guide (the 'Orange Guide') for blood.

The key points, relevant to the Hospital Blood Bank, can be viewed at: - <http://hospital.blood.co.uk/library/pdf/training_education/GMPGuide.pdf>

## 1.2 Quality Manual - Organisation

This Quality Manual describes the Quality Management System (QMS) of the Department of Haematology, Clyde Sector, NHSGGC (the “Department”). Throughout the text there are references to **ISO: 15189** Standards (prefixed **ISO**), and to the Standards and requirements of the **Blood Safety & Quality Regulations** (2005) (prefixed **BSQR**), as indicated by round brackets, and to Departmental policies and procedures **[indicated by square brackets]** written in fulfilment of these standards.

This Quality Manual can be regarded as the index volume to separate management, laboratory, and quality policies and procedures, and forms. The sections of the Quality Manual are arranged so that they equate with the ISO: 15189 Standards. Under the title of each standard, 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 procedures.

|  |  |
| --- | --- |
| **Quality Manual** | **ISO: 15189 Standards** |
| **Section 2** | **4 Management Requirements** |
| 4.1 Management Responsibility |
| **Section 3** | 4.2 Quality Management System |
| **Section 4** | 4.3 Document Control |
| **Section 4.2** | 4.4 Service Agreements |
| **Section 5** | 4.5 Examination by Referral Laboratories |
| **Section 6** | 4.6 External Services and Supplies |
| **Section 7** | 4.7 Advisory Services |
| **Section 8** | 4.8 Resolution of Complaints |
| **Section 9** | 4.9 Identification and Control of Non-Conformities |
| **Section 10** | 4.10 Corrective Action |
| 4.11 Preventative Action |
| **Section 11** | 4.12 Continual Improvement |
| **Section 12** | 4.13 Control of Records |
| **Section 13** | 4.14 Evaluation and Audits |
| **Section 14** | 4.15 Management Review |
| **Section 15** | **5 Technical Requirements** |
| **Section 15.1 – 15.5** | 5.1 Personnel |
| **Section 16** | 5.2 Accommodation & Environmental Conditions |
| **Section 17** | 5.3 Laboratory Equipment, Reagents & Consumables |
| **Section 18** | 5.4 Pre-Examination Processes |
| **Section 19** | 5.5 Examination Processes |
| **Section 20** | 5.6 Ensuring the Quality of Examination Results |
| **Section 21** | 5.7 Post-Examination Processes |
| 5.8 Reporting of Results |
| 5.9 Release of Results |
| **Section 22** | 5.10 Laboratory Information Management |

The elements of the ISO: 15189 standard can be seen to relate to each other with processes linked, inclusive of requirements for continuous evaluation and quality assurance. The results feed back to maintain, and where required, improve the quality management process and to ensure that the needs and requirements of users are met.

# 2.0 Organisation & Management Responsibility (ISO 4.1)

The Department of Haematology, Clyde Sector, and NHSGGC (herein referred to as “the Department” shall meet the requirements of BN ISO: 15189 (**ISO 4.1, 4.1.1.1**), when carrying out work at from facilities defined in this Quality Manual.

## 2.1 Legal Identity (ISO 4.1.1.2, TPS-51 [MI-CGEN-054])

The Department of Haematology, Clyde Sector, NHSGGC, a sub-division of the Diagnostics Directorate, Acute Services Division, NHSGGC (see Section 2.4.5), is represented and is comprised of laboratories situated at the Royal Alexandra Infirmary (RAH), Inverclyde Royal Hospital (IRH), and the Vale of Leven Hospital (VOL) -

|  |  |
| --- | --- |
| **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. |

## 2.1.1 Contact Information

Contact information is available via the Laboratory Handbook (Service User Handbook) **[MF-CGEN-022]**.

## 2.1.2 Hours of Operation

See Laboratory Handbook **[MF-CGEN-022]** for information.

## 2.1.3 Service Provision

The Department serves to provide a comprehensive range of Haematology and Blood Transfusion related investigations with clinical and interpretative support and referral to other laboratories where clinically appropriate. This is outlined within the user manual. As outlined within the Departmental Quality Policy, the department aims to provide a prompt, quality assured and clinically relevant analytical and consultative service.

# 2.2 Ethical Conduct & Financial Administration (ISO 4.1.1.3)

In compliance with NHSGGC Policy, the Department operates a strict budgetary control and purchasing policy, as outlined within “Standing Financial Instructions” (accessed via StaffNet) -

<http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Finance/Financial%20Governance/Pages/default.aspx>).

The NHS GG&C Code of conduct for staff outlines the ethical conduct expected of staff and can be accessed via the link below

<http://www.nhsggc.org.uk/media/235574/code-of-conduct-for-staff-may-2015.pdf>

# 2.2.1 NHSGGC Managed Service Contract

The Diagnostics Division, NHSGGC, is contracted with Abbott for the provision of a “Managed Service Contract”.

# 2.2.1.1 Procurement of New Equipment [MP-CGEN-010]

Consistent with NHSGGC Policy, accessed via StaffNet - <http://www.staffnet.ggc.scot.nhs.uk/Acute/Procurement%20Department/Corporate/Pages/default.aspx>,

Departmental Policy [**MP-CGEN-010**] serves to define procedures relating to the procurement and management, inclusive of maintenance and service, of Laboratory Equipment.

# 2.3 Laboratory Director - Professional Direction (ISO 4.1.1.4)

NHSGGC require that a **Consultant Haematologist** (**Site Lead Clinician**) professionally directs each Haematology / Blood Transfusion Laboratory, operating within the Clyde Sector, NHSGGC (Clyde Sector comprises - Royal Alexandra Hospital (RAH), Inverclyde Royal Hospital (IRH), and, Vale of Leven Hospital (VOL).

As further defined within Consultant Job Descriptions / Job Plans, each consultant is professionally responsible and managerially accountable to the **Sector Lead Clinician**, who is professionally responsible and managerially accountable to the **Head of Service**.

Outlined below are the Lab director duties, or delegated duties as appropriate, under (**ISO 4.1.1.4):**

|  |  |  |
| --- | --- | --- |
| **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. | Lead Clinician, 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. | Lead clinician, 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. | Lead Clinician |  |
| 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. | Lead Clinician, 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. | Lead Clinician, 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. | Lead Clinician, 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. | Lead Clinician, 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. | Lead Clinician, TSM and Sector Lab Manager |  |

The **Technical Services Manager** and **Sector Laboratory Manager** are professionally responsible and managerially accountable to the **Sector Lead Clinician**, and to the **General Manager**, Diagnostics Directorate, NHSGGC.

# 2.3.1 Clinical Commitments & Clinical Consultation and (ISO 4.7) see section 7.0

## 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 2.4.5.4 Divisional Management Structure – Haematology, Clyde Sector.

The Department provides a comprehensive routine and specialised haematology service (see also Section 7.0) from all hospital sites that comprise the Clyde Sector, as defined in Section 2.1.

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.

# 2.3.1.1 Out of Hours Clinical Consultation and Advisory Service

## 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.

## 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.

# 2.4 Management Commitment & Responsibility (ISO 4.1.2)

# 2.4.1Management Commitment (ISO 4.1.2.1)

Consistent with UKAS requirements, the Department is committed to the development and implementation of the quality management system and continually improve its effectiveness by:

1. Communicating to laboratory personnel, the importance of meeting the needs and requirements of users – see Section 3.7.2, as well as regulatory and accreditation requirements;
2. Establishing a Quality Policy (**ISO 4.1.2.3**) - see Section 3.7.3;
3. Ensuring that quality objectives and planning are established (**ISO 4.1.2.4**) – see Section 3.7.4;
4. Defining responsibilities, authorities and interrelationships of all personnel (**ISO 4.1.2.5**) – see Section 3.0, and establishing communication processes (**ISO 4.1.2.6**) – see Section 3.7.5;
5. Appointing a Quality Manager (**ISO 4.1.2.7**) – see Section 3.7.6;
6. Conducting Management Reviews (**ISO 4.15**) – see Section 3.7.8;
7. Ensuring that all personnel are competent to perform their assigned activities (**ISO 5.1.6**);
8. Ensuring availability of adequate resources (**ISO** **5.1, 5.2 and 5.3**) to enable the proper conduct of pre-examination, examination and post-examination activities (**ISO 5.4, 5.5, and 5.7**).

# 2.4.2 Needs of Users (ISO 4.1.2.2, 4.1.2.6, 4.4, and, 4.14.3)

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

The needs of the users are kept under constant review, achieved through periodic meetings (HTC), informal discussion and communication, and from user surveys / questionnaires performed periodically as part of scheduled Departmental audit activity.

User needs and requirements, including complaints, are discussed as a standing agenda, at the Haematology Management Team meetings and the Departmental Quality Team Meeting. Where appropriate, user needs form the focus of objective setting and planning within in the Quality Management System.

The Department, in accordance with Divisional governance policies and procedures, operates a Departmental Policy [**MP-CGEN-006**], with associated defined procedures for the management, assessment and review of complaints (**ISO 4.8**).

# 2.4.3 Quality Policy (ISO 4.1.2.3)

The Department is committed to providing a service of the highest quality, taking into account resource provision, and shall be aware and take into consideration the needs and requirements of all service users.

The Quality Policy, formally reviewed at the Annual Management Meeting [**MP-CGEN-015**], is given below and published as a separate controlled document [[**MP-CGEN-007**](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-014.QualityPolicy.doc)] for display within the laboratory.

|  |
| --- |
| **The Department of Haematology / Blood Transfusion, Clyde Sector, NHS Greater Glasgow & Clyde, is committed to the provision of a comprehensive Clinical & Analytical Service of the highest quality. With this aim, the Department shall:*** Operate a Quality Management System to integrate the organisation, its staff, procedures, processes and resources.
* Set and review quality objectives and plans in order to implement this Quality Policy, and to assure continual quality improvement of the service.
* Annually, as a minimum, review the suitability and effectiveness of this Quality Policy.
* Ensure that Departmental personnel are familiar with the Quality Manual, this Quality Policy, and related procedures and processes relevant to their work.
* Commit to the health, safety and welfare of all staff and visitors to the Department, in compliance with NHSGGC and National Legislation.
* Commit to NHSGGC and National Legislation relating to the environment.
* Uphold professional values and be committed to good professional practice and conduct.

The Department is committed to maintaining compliance with quality standards, as set principally by UKAS (ISO 15189 and associated standards), and MHRA, Good Laboratory Practice, and including all other relevant quality standards. With this aim, the Department shall operate and regularly review systems for:* Staff recruitment, training, development and retention, at all levels, to assure good professional practice, and the provision of a full and effective service to users of the service.
* The procurement and maintenance of equipment and other resources as required for the provision of the service.
* The collection, transport and handling of laboratory specimens in such a way as to ensure the correct performance of laboratory examination procedures.
* Validation and review of examination procedures to assure the highest achievable quality of all tests performed.
* The reporting of results of examinations in ways which are timely, confidential, accurate and clinically useful, and that meet with the requirements of service users.
* The assessment of user satisfaction and the implementation of systems for internal audit and quality assessment (internal Quality Control, and external Quality Assurance) to benchmark and improve service quality.
 |

# 2.4.4 Quality Objectives and Plans (ISO 4.1.2.4)

Laboratory Management are required to ensure effective planning of the Quality Management System (QMS) is performed, consistent with quality objectives, and that the integrity of the QMS is maintained.

Quality objectives, for each laboratory, inclusive of the requirement to ensure that plans are defined to in response to objectives, are set by the Haematology Management Team in consultation with the individual departments. At Departmental level, Quality Objectives form a routine element of every departmental meeting. The setting and planning, inclusive of the evaluation of effectiveness, of Quality Objectives, however, forms a defined function of the Departmental Annual Management Review Meeting [MP-CGEN-015] (ISO 4.1.2.1, 4.15), and the Departmental Quality Team Meeting. See also:

* See Section 3.3 – Quality Management System Objectives and Plans (ISO 4.2),
* See also Section 11.0 - Quality Improvement Framework & Quality Indicators (ISO 4.12).

## 2.4.5 Responsibility, Authority and Interrelationships (ISO 4.1.2.5)

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

**Mr. J. Best**

Chief Operating Officer, Acute Services, NHSGGC

**Mr. Rob Gardiner**

General Manager, Diagnostics, NHSGGC

**Mr. A Williams**

Director of Diagnostics, Acute Services, NHSGGC

**Dr. R. Green**

Associate Medical Director, Diagnostics Directorate, Acute Services, NHSGGC

**Dr. F. Patrick**

Sector Lead Clinician, Haematology / Blood Transfusion, Clyde Sector, NHSGGC

**Ms. J. Gibb**

Assistant General Manager, Blood Science & Immunology, Diagnostics, NHSGGC

**Dr. E. Fitzsimons**

Head of Service, Haematology / Blood Transfusion, NHSGGC

**Mr. M. Wight**

Technical Services Manager, Haematology / Blood Transfusion, Clyde Sector, NHSGGC

**Dr. A. Leonard**

Clinical Director, Diagnostics Directorate, NHSGGC

**Dr. A. Sefcick**

Site Lead Clinician, Department of Haematology / Blood Transfusion, RAH

**Dr. F Patrick**

Site Lead Clinician, Department of Haematology / Blood Transfusion, IRH

**Dr. C Sweeney**

Site Lead Clinician, Department of Haematology / Blood Transfusion, VOL

Medical Staff, Haematology / Blood Transfusion, Clyde Sector, NHSGGC

**Ms. P. Bradley**

Laboratory Manager, Haematology / Blood Transfusion, Clyde Sector, NHSGGC

**Mr. G.D. Walker**

Quality, Training & POCT Manager, Haematology / Blood Transfusion, Clyde Sector, NHSGGC

**Mr. D. Dunlop**

Chief Operating Officer, Regional Services, NHSGGC

**Dr F. Patrick**

Designated responsibilities for Hospital Blood Banking & Blood Transfusion

Lead Consultant Clinician – Dr. A. Sefcick who is responsible for all RAH clinical matters and is supported by Dr. F. Patrick (site lead for IRH) and Dr. C. Sweeney (site lead for VOL).

Lab Consultant lead – Dr. F. Patrick is the laboratory lead consultant with responsibility for Blood Transfusion.

Technical Services Manager (TSM) – Martin Wight (Deputises for SM) who is responsible for all Technical and laboratory matters and reports to the assistant general manager (Jane Gibb).

Sector Manager (SM) – Patricia Bradley (Deputises for TSM and QM) who has special responsibility for Blood Transfusion matters and reports to the TSM.

Quality Manager (QM) – Graham Walker who is responsible for all Quality, Training and Point of Care matters and reports to the TSM.

**2.4.5.1 Departmental Staff – Key Responsibilities (ISO 4.1.2.5)**

|  |  |
| --- | --- |
| 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. |
| Sector Laboratory Manager | Responsibilities of the Sector Laboratory Manager are defined in [**MI-CGEN-011**]. Responsibilities include the role of Deputy to the Quality, Training and POCT Manager. |
| Quality, Training and POCT Manager | Responsibilities of the Quality, Training and POC manager are defined in [**MI-CGEN-012**] |

## 2.4.6 Health and Safety

The department is committed to manage its activities in a safe manner in accordance with the Health and Safety at Work Act (1974), Management of Health and Safety at Work Regulations (1999), and other statutory legislation and guidance.

The Chief Executive has overall responsibility for the Health and Safety of all staff, visitors and patients of NHSGG&C. All Divisional staff are charged with responsibility for their own safety and that of others. It is also the responsibility of staff to participate in the promotion of Health and Safety in the workplace. NHSGG&C, through distribution of the “Health and Safety Control Book” (Management Manual), to Managers with designated Health and Safety responsibilities, provides a vector for communication of requirements, whilst at the same time, providing a mechanism for audit of the effectiveness of local Health and Safety Management. The Control Book is subject to annual audit by the Divisional Risk and Health and Safety Managers.

## 2.4.6.1 Responsibilities of Laboratory Management

The departmental Health and Safety Code of Practice [**HP-CGEN-001**] serves to communicate Health and Safety information, departmental policies and procedures, inclusive of roles and responsibilities, to departmental Staff. Staff are given access to this document at induction.

# 2.4.6 Communication and Departmental Meeting Program (ISO 4.1.2.6)

Meeting Minutes form the principle means to communicate Meeting content, inclusive of defined Action Limits, those responsible for their completion, their associated timescale, are recorded using a template report Form [**MF-CGEN-019**]. In addition, Meeting Minutes, inclusive of Action Points are communicated to staff via: other meetings; by email; and, upload to “common” Network Location (“shared drive” – with access to Meeting Minutes, restricted to named departmental Staff, as appropriate).

# 2.4.6.1 – NHSGGC Corporate Communications and StaffNet

The NHSGGC Corporate Communications Strategy (accessed via StaffNet) serves to ensure that NHSGGC communication activities are effectively and efficiently channelled to support the delivery of the organisation's goals and priorities – see –

<http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Communications/Briefs/Documents/Corp%20Comms%20Strategy_final.pdf>

Key principles include the essential communication of NHSGGC Strategy, inclusive of service and or organisational change, via Staff Newsletters, and Team, and Core Brief.

# 2.4.6.2 Management Meetings

The Department co-facilitates, consistent with reporting processes as defined by the Haematology Management Team, a series of formal management meetings, involving both senior Departmental and senior Hospital Management (parent organisation) staff that serve to review the service, set objectives, and make appropriate financial arrangements.

* A direct line of reporting is established, through the Technical Services Manager, who reports directly to the Haematology Management Team, with responsibilities to report to the Laboratory Directorate Executive Board, and the Board of Directors, NHSGGC.
* Divisional Management meetings are held in Partnership, with Partnership representatives in attendance.
* Meetings are typically coordinated via a Standing, or approved, Agenda, to include:
* Apologies for absence
* Minutes of previous meeting held on (date)
* Matters arising from the minutes
* Discussion items 1, 2, etc,)
* Any Other Competent Business (AOCB)
* Date and time of next meeting

**a) NHSGGC Haematology Management Team (HMT)**

The remit of the Haematology Management Team, meeting on a monthly basis, is to administer and review resource, clinical effectiveness and audit within the Department of Haematology, to oversee and align strategy within the Laboratories Directorate.

**b) NHSGGC Overarching Transfusion Committee**

See Section 2.4.6.3.

**c) NHSGGC Point of Care Testing (POCT) Committee**

The remit of the NHSGGC POCT Committee (and Sector sub-Committee’s) is defined within the NHSGGC POCT Policy **[MI-CGEN-016]**, and meets bi-annually to administer and facilitate the safe and effective use of “Near Patient Testing” in accordance with current guidelines and legislation. The Committee Chair reports to the NHSGGC Diagnostics Clinical Governance Committee.

**d) Clyde Sector (Multi-Disciplinary) Health and Safety Group**

The remit of the Clyde Sector Multi-Disciplinary Health and Safety Group, meeting on a quarterly basis, is to oversee and align Health and Safety strategy across Diagnostics, Clyde Sector, and to ensure compliance with NHSGGC, and National, Health & Safety policy and practice.

# 2.4.6.3 Departmental Meetings

Departmental Meeting Minutes form the principle means to communicate Meeting content, inclusive of defined Action Limits, those responsible for their completion, their associated timescale, are recorded using a template report Form [**MF-CGEN-019**],

**a) Haematology Quality Team Meetings**

As further defined in **[MP-CGEN-017]**, the Departmental Quality Team serves to establish, evaluate, and ensure an integrated approach to Quality Assurance inclusive of Departmental Quality Strategy, Quality Improvement, User Feedback and Complaints, and Quality Objective setting, and the evaluation and setting of Key Performance Indicators (including audit), consistent with Quality Policy.

**b) Haematology – Senior Staff Meetings**

Senior Staff meetings are held monthly to discuss, evaluate, and to communicate organisational, professional and technical policy and procedures.

**c) Clyde Sector Haematology – General Staff Meetings**

General Staff Meetings are held monthly at RAH (covers VOL) and IRH, to discuss, evaluate, and to communicate organisational, professional and technical policy and procedures. Quality issues, inclusive of NC logs, Datix, IQC and EQA are discussed as well as UKAS and MHRA status, form standing agenda items as does training status and workforce planning.

# 2.4.6.4 Blood Transfusion Meetings

**a) NHSGGC Overarching Transfusion Committee**

The remit of the Overarching Transfusion Committee (OATC), meeting on a quarterly basis, is to review and ensure commonality in, and to oversee the safety and effectiveness of the Hospital Blood Banking service. In addition, the Committee serves to align Blood Banking strategy in accordance with current guidelines and legislation, and to set and administer NHSGGC Transfusion Policy (see NHSGGC Transfusion Policy **[LI-CBTR-004]**).

Reporting to the Haematology Management Team, the OATC includes representation from the Scottish National Blood Transfusion Service, individual Hospital Transfusion Committee’s, and the NHSGGC Transfusion Practitioners.

**b) Clyde Sector - Hospital Transfusion Team Meetings**

Monthly Hospital Transfusion Team (HTT) meetings, in accordance with Departmental & NHSGGC Divisional Policies (further defined within **[MP-CGEN-005]),** serve to facilitate:

* Evaluation, review, and where appropriate, the institution of preventative and corrective action, in relation to Blood Banking and Transfusion related process and process change, audit and education requirements,
* Set and evaluate Blood Transfusion related performance indicators, inclusive of risk and incidents, and Quality Deviation Incidents.
* Report near miss and critical incidents to the Divisional Risk Manager, and where appropriate, to external agencies such as SHOT / SABRE / etc.
* Escalate, using the Departmental Risk Register, risks and incidents not satisfactorily “closed” by the HTT to the Haematology Management Team.

Meeting minutes are prepared by the Technical Services Manager.

**c) Clyde Sector - Hospital Transfusion Committee**

The Hospital Transfusion Committee (HTC), meeting on a quarterly basis, function to review and oversee the safety and effectiveness of the Hospital Blood Banking / Transfusion service, and to facilitate a safe and efficient transfusion service, at Hospital level, consistent with National and International Blood Banking Legislation and Guidelines, such as the Better Blood Transfusion Program, the Blood Safety & Quality Regulations **[MP-CGEN-018]**, UKAS (ISO: 15189), and so on.

# 2.4.7 Quality Manager (ISO 4.1.2.7)

As fully defined in the Quality Manager Job Description [MI-CGEN-012], 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.

Accountable to the Technical Services Manager, the Quality Manager [**MI-CGEN-012**] is responsible for the development and maintenance of the QMS.

# 3.0 Quality Management System (ISO 4.2)

# 3.1 Documentation Requirements (ISO 4.2.2)

QMS documentation shall include:

1. A Quality Policy (**ISO 4.1.2.3**) and Quality Objectives (**ISO** **4.1.2.4**);
2. A Quality Manual (**ISO4.2.2.2**);
3. Procedures & Records - Documentation can be in any form or type of medium, providing it is readily accessible and protected from unauthorised changes and undue deterioration.

# 3.2 Quality Manual (ISO 4.2.2.2) (requirements fulfilled by this document)

The Quality Manual includes:

1. The quality policy (**ISO 4.1.2.3**) 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.

# 3.3 Quality Management System Objectives and Plans (ISO 4.2)

|  |  |
| --- | --- |
| **Quality Policy (4.1.2.3)** | The Quality Policy communicates to staff, quality as an integral element of the design, development and delivery of the service, as provided by the Department of Haematology, NHSGGC. The Department emphasises the use of problem prevention and problem correction in order to provide a quality service to Department Users. |
| **Objectives (4.1.2.4)** | Are established locally or within the Diagnostics Directorate. There are set out annually at the Annual management review and updated as and when required. |

# 4.0 Document Control (ISO 4.3)

## Is fulfilled by [MP-CGEN-002]:

These documented policies and procedures are controlled and effectively implemented to ensure that Departmental User requirements are satisfied. This documentation serves to ensure:

Procedures necessary for the proper performance of laboratory examinations, and consultation, are readily available to relevant staff both inside and out with the Department.

QMS documentation is subject to strict management control, and subject to defined review and amendment, as appropriate.

* 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 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)

The QMS document management system (Q-Pulse, Ideagen Ltd) – software functionality and aspects of electronic document control are defined in [**MP-CGEN-002**].

# 4.1 Service Level Agreement (SLA) (ISO 4.4)

The requirement to formally define service user requirements, inclusive where appropriate, of formal contract (SLA), is identified by the Department as an essential prerequisite of a quality service.

SLA is hence considered as part of the negotiation of a service contract, whose endpoint is an agreement applicable and agreed between the Department and the user organisation, andwhere the level of service is formally defined.

The Department acknowledges that:

* Each request accepted by the laboratory for examination(s) shall be considered an agreement.
* Agreements to provide medical laboratory services (as defined by Test Request / Order, either by Hard Copy Request Form, or by electronic requesting systems) shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation.

The Department operates standardised protocols [**MP-CGEN-013**] for the establishment, review, and administration of SLA’s.

# 5.0 Examination by Referral Laboratories (BSQR, ISO 4.5)

**Accreditation systems stipulate requirements to ensure that subcontractors used, be recognised or accredited institutions, and known to the referring Department.**

The Departmental Examination Referral Policy [**MP-CGEN-014**] serves to outline the general requirements for sample handling, packaging and dispatch, as well as procedures for the recording of the sending of laboratory specimens to referral laboratories for testing, and the subsequent management of results and reports received from referral laboratories – in summary this Policy serves to assure:

* Evaluation and selection of referral laboratories (**ISO 4.5.1**) in terms of competence to perform referred examinations,
* The maintenance of a record to cover all analyses referred, and the testing laboratories that samples are referred to [**MI-CGEN-031**],
* Records of referrals include dates of dispatch, the transport route, and details of the referral laboratory,
* The monitoring of results and reports as issued by referral laboratories,
* The definition of 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.

In addition to the above, ISO and also, the Blood Quality & Safety Regulations (**BSQR**) **[MI-CGEN-064]**, stipulate additional requirements to ensure where laboratory management enters into a formal agreement to provide medical laboratory services, it shall establish a documented procedure for the establishment and review of such agreements – Departmental Policy, in compliance, is defined in [**MP-CGEN-013**].

# 5.1 Reports from Referral Laboratories (ISO 4.5.2)

1. Reporting procedures, for all referred analyses, are detailed in [**LP-CHAE-002]** (Haematology Tests), and [**LP-CBTR-014**] (Blood Transfusion Tests) – Laboratory Procedures for Referred Analyses.
2. For reports that are entered to the Departmental LIMS (Computer), or, where results from referral laboratories may be incorporated to another report, the following principles apply:
	* Details of the testing (referral) laboratory **must** be entered to indicate what tests were performed by the referral laboratory,
	* **All results, interpretative comments, etc**, as issued by the referral laboratory, must be entered with the report,
	* Where the referral laboratory issues a detailed and lengthy report, an abbreviated version may be entered on the LIMS, as long as the original full report is forwarded to the requesting clinician for filing in the patient’s case record. In this event - the LIMS report should be identified as an abbreviated report.
3. Where reports from referral laboratories are transcribed to the LIMS, or incorporated into any other reporting format, reports **must** be checked against the referral laboratory report to assure accurate transcription of results and report comments.
4. Departmental Reports shall 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.
* Where results from referral laboratories need to be transcribed, e.g. to the LIMS, procedures for the verification of correct transcription.

# 6.0 External Services and Supplies (ISO 4.6, 5.3)

The Department facilitates procedure for the selection and purchasing of equipment [**MP-CGEN-010**], and reagents, calibration and quality control materials, and consumable supplies [**MP-CGEN-011**] that have the capacity to affect the quality of the service.

NHSGGC operates a system of strict budgetary control, as detailed within NHSGGC Standing Financial Instructions. In accordance with this system, the purchasing of supplies, by the Department, is controlled through authorised staff use (password controlled) of the software-based purchasing systems – “PECOS”.

In addition to this, a system for Internal Supplies Ordering, used for the indenting of general and office supplies from the Hospital Stores and Pharmacy Department operates. The policies and procedures for use of this system, facilitated through on-line requisition forms, are again outlined within the aforementioned Standing Financial Instructions.

In addition, many laboratory supplies, including reagents, calibration and quality control material, are purchased through standing order contract (e.g. Managed Service Contract) with the supplier company.

The Department:

* Satisfactorily selects and approves suppliers based on their ability to supply services, equipment, reagents and consumable supplies, in accordance with contracted requirements,
* Compliant with NHSGGC Policy, operates strict purchasing control procedures,
* Shall purchase goods, services, equipment and materials only from a list of selected and approved suppliers,
* Shall monitor the performance of suppliers to ensure that purchased services or items consistently meet contracted criteria.

# 7.0 Advisory Services (ISO 4.7)

The Department provides a comprehensive routine and specialised Haematology service with the Departmental Medical Team serving to provide a clinical consultation and advisory service both for hospital inpatients and patients in General Practice. Patients may be directly referred for medical opinion, or the team may suggest consultation following from the review of analytical results. The team works in close collaboration with other clinical colleagues, where relevant, to ensure optimal combined clinical and laboratory input to patient investigation and management. Specific contact details can be accessed via the Service User Handbook, [**MF-CGEN-022**], (accessed by Service Users via StaffNet or hard copy).

# 8.0 Resolution of Complaints (ISO 4.8)

Departmental Policy for Complaints [**MP-CGEN-006**] 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.

Complainants 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 issue, should be directed to contact the NHSGGC Complaints Team, by telephoning 0141 211 511, or by writing to:

NHSGGC Complaints Team,

Glasgow Royal Infirmary,

84, Castle Street,

GLASGOW, G4 0SF

# 9.0 Identification & Control of Non-Conformity (ISO 4.9)

To facilitate a comprehensive and systematic approach towards corrective, and or preventative action (CAPA), this document serves to define procedures and responsibilities for the reporting of non-conformance, corrective actions, implementation of process change, where appropriate, and subsequent review / audit, using the Q-Pulse Audit and Non-Conformance Modules. Procedures specific to the use of the Q-Pulse CAPA Module are defined in [**MI-CGEN-021**].

Departmental Quality Assurance Policy and procedures [**MP-CGEN-017**] defines procedures for the identification, control and administration of non-conformity.

# 9.1 Departmental Non-Conformity Definition & Categorisation

In accordance with both UKAS (ISO: 15189) and MHRA (BSQR) requirements, the department has a policy which describes its risk and incident management processes [**MP-CGEN-005**].

# 9.3 Root Cause Analysis (4.10b)

Stemming from Risk and Incident Management Policy and Procedures [**MP-CGEN-005]**, and further defined in [**LI-CGEN-020]**, the Department, using the Q-Pulse CAPA Module (see also [**MI-CGEN-021]**) operates a systematic approach to the analysis of “Root Cause” (**4.10b**).

# 10.0 Corrective and Preventative Action (CAPA) (4.10 and 4.11)

ISO: 15189 requirements for Corrective Action are defined in **4.10 Corrective Action**.

Departmental procedures for the reporting and administration of CAPA, using the Q-Pulse CAPA Module are defined in [**MI-CGEN-021**].

# 11.0 Continual Improvement Framework (ISO 4.12, 4.14.7)

[**MP-CGEN-017**] defines a series of Quality Indicators / Performance Assessment Tools (inclusive of details relating to the methodology of assessment and the duration of measurement), broken down into pre-analytic, analytical, and post-analytical phases, that together serve as an elementary framework to be audited, as part of the internal audit program, and as a vector for the assessment of service Quality and Improvement, and, the setting of Quality Objectives and Plans.

# 12.0 Control of Records (ISO 4.13)

The Department operates a procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records [**MI-CGEN-042**] and [**MP-CGEN-003**], and to ensure that records shall be created concurrently with performance of each activity that affects the quality of the examination. Additionally, Standards require 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 (**ISO 5.8.6**).
* 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 (**ISO 5.2.6**).
* For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location (**ISO 5.9.4**).

# 12.1 Control of Clinical Material

Departmental Policy [[**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)] 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.

# 13.0 Evaluation, Quality Assurance and Audit (ISO 4.14)

# 13.1 General Information (ISO 4.14.1)

This is the continual audit and evaluation of all internal and supporting processes for the department to meet the requirements of the users.

## Assessment of User Satisfaction (ISO 4.14.2, 4.14.3)

Accreditation systems, including ISO, stipulate a specific requirement for policies and procedures for the assessment of user satisfaction (the laboratory shall seek information), and complaints and for the periodic review of requests, the Departmental laboratory and advisory services, inclusive of the suitability of Examination Procedures, and specimens required (**ISO 4.14.2**).

For the Department, this is achieved through user liaison, both informal and as part of formal meetings and discussions, and communications, and from user surveys / questionnaires performed periodically as part of Departmental audit activity. User needs and requirements, including complaints, are routinely discussed by the Departmental Quality Team Meeting as a standing agenda, where user needs are formally evaluated and translated into requirements, which form the focus of objective setting and planningwithin in the Quality Management System. User requirements are also routinely discussed at Departmental Senior and General Staff Meetings, as appropriate. Lastly, summary reports relating to user requirements, and associated performance objectives and improvements, form a standing agenda of the Departmental Annual Management Review Meeting.

## Staff Suggestions – Quality Improvement Note (ISO 4.14.4)

As further defined in [**MP-CGEN-017**], the department can use the “Improvement Ideas” reporting function of Q-Pulse for staff (and Service User) quality improvement suggestions. There is also a staff suggestion form [**QF-CGEN-047**] which can be used and there is an annual staff survey and action plan generated using the GG&C ‘iMatter’ programme.

## Internal Audit of the Quality Management System (ISO 4.14.5)

As further defined in [**MP-CGEN-017**], the Quality Manager is responsible for scheduling and coordination of internal audits, and for ensuring that audits have been conducted in accordance with defined protocols.

In accordance with ISO: 15189, 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 work being audited.

For the Department, audit of the QMS includes:

* **Pre - Analytical Phase**

Audit includes aspects of sample collection, transportation, and receipt by the Laboratory (specimen reception).

* **Analytical Phase**

Audit of Examination Procedures ensures:

1. Appropriate procedures for Quality Control and performance monitoring are defined,
2. Means of control, the timing of control and the criteria for result validation, are defined,
3. Test Results are validated (and reported) only following acceptable Quality Control,
4. Test turnaround time meets with user requirements,
5. New test methods (Examination Procedures) are validated prior to the introduction to the Departmental test repertoire, and hence, prior to routine use.
	* **Post - Analytical Phase**

Audit of the post – analytical phase includes the review of reporting mechanisms, and clinical and consultative advice.

The planning and scheduling of Internal Audit of the QMS forms a key role of the Quality Manager, and is detailed year on year using the Q-Pulse Audit Module. Three main types of audit, designed to provide a comprehensive cover of the QMS, are employed:

## Horizontal Audit

Using a pre-scripted electronic Audit Checklist (facilitated by the Q-Pulse Audit Module) or, using standard form [[**QF-CGEN-011**](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\QUF-ALL-ALL-004.HorizontalAuditForm.doc)], this is a detailed check of a particular component part of (or a horizontal slice through) the QMS.

## Examination Audit

Using a standard form [[**QF-CGEN-012**](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\QUF-ALL-ALL-005.ExaminationAuditForm.doc)], this is when an Examination Procedure or Laboratory Work Instruction is witnessed as it is performed. There are two objectives in such an audit. Firstly, to ensure that what is being done reflects what is described in the procedure, and secondly, that the person carrying out the Examination Procedure or Laboratory Work Instruction has a good understanding of all aspects of the procedure, and is performing the procedure correctly.

Additionally, Examination Audit is routinely performed as part of staff competency assessment (as a set Competency Assessment Exercise, and or, as part of the Departmental Staff Training Program), as further defined in the Training Policy [**MP-CGEN-019**].

## Vertical Audit

Using a pre-scripted Audit Checklist (facilitated by the Q-Pulse Audit Module), or, using a standard form [[**QF-CGEN-012**](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\QUF-ALL-ALL-005.ExaminationAuditForm.doc)], this is a detailed check that all elements associated with a chosen Examination Process are implemented. The principle is that all activities contributing to the final report would be audited for conformance with the laboratory’s pre-examination, examination, and post-examination processes.

## Risk Management (ISO 4.14.6)

Risk management, an identified key component of effective Clinical Governance, incorporates a systematic approach to:

* Identifying risks (to staff, service users, patients, and fellow health care professionals),
* Analysis of adverse clinical incidents, indemnity claims, and complaints,
* Control of risks by use of systems and checking procedures.

The Department operates a Risk & Incident Management Policy [**MP-CGEN-005]** that includes a systematic process (including audit of Premises and Environment and Health and Safety) whereby risks to staff, service users, patients, and fellow health care professionals are reported, investigated and acted upon appropriately and promptly. As stipulated in the Departmental Policy, incidents and risks, inclusive of complaints, Quality Deviations, and service quality improvement, are reported and reviewed at the Departmental Quality Team Meeting.

## External Quality Assurance

The Department identifies ([**MP-CGEN-017**]) the participation in External Quality Assurance Assessment Schemes (EQAS), as an essential element in informing Service Providers and Service Users, the quality of output provided by the Department.

Further to this, the Department participates in approved EQAS, where available, appropriate to the Departmental test repertoire. Departmental procedures relating to External Quality Assurance, including: recording of results; performance monitoring; the communication of results to staff; the institution and recording of corrective actions; and the Departmental review mechanisms, are detailed in each Examination Procedure SOP, and also, in [**LP-CGEN-004**].

In addition, when a formal inter-laboratory comparison programme is not available, the laboratory shall develop systems for determining the acceptability of procedures not otherwise evaluated.

## External Audit or Review by External Organisations (BSQR, ISO 4.14.8)

## MHRA and the BSQR

Details of the MHRA Inspection process are defined - <http://www.transfusionguidelines.org.uk/regulations/toolkit/mhra-process/mhra-inspection-process>

## UKAS and ISO: 15189

Full details of the UKAS assessment process, the requirements of ISO 15189, and scheme participants, can be accessed via [http://www.ukas.com](http://www.ukas.com/). The Accreditation and Process is essentially defined by two key UKAS Reports:

# UKAS Gen 1 – General Principles for the Assessment of Conformity Assessment Bodies by the United Kingdom Accreditation Service

# [MI-CGEN-086] serves to fully define and provide general guidance on the conduct of UKAS in the performance of laboratory assessments: the “main” UKAS Assessment Visit, and Surveillance and Re-Assessment Visits.

In addition, [**MI-CGEN-086**] provides guidance on the assessment and accreditation of multi-site laboratories and describes how UKAS will assess and make reference to multi-site laboratory accreditations.

NOTE - for the following,

* the term “Department” is used to indicate the “Department of Haematology, Clyde Sector, NHSGGC),
* the term “Clyde-wide” is used to indicate documentation, policy, procedures, etc, that apply across the Clyde Sector, and hence are applicable at each hospital location:

|  |  |  |
| --- | --- | --- |
|  | **UKAS Requirement** | **ISO 15189 (2012) Standard met by:** |
|  | **Define the relationships between the locations and the organisation and responsibilities of key staff** | Section 2.0 of this Manual details:* + The legal identity, address(es) and hospital sites that constitute the Department (Clyde Sector),
	+ Key Contact Information,
	+ The Working Hours of the Department,
	+ A definition of the service, across the Clyde Sector,
	+ The Departmental Test Repertoire, and what tests are provided on each hospital site,
	+ Policy and procedures for Ethical and Financial Administration of the Department,
	+ The Sector, and Hospital Site, Lead Clinician(s), and the Departmental Management Team, with Organisational charts to define operational management for each staff member to the CEO, NHSGGC. Organisational charts also serve to define reporting links of the Department to the General Manager, Diagnostics Division, NHSGGC,
	+ Details relating to the Clinical Advisory Service (see also Section 19.2.2 of this Manual).
 |
|  | **Staff Training & Competency** | See also – Section 15 of this Manual. Clyde-wide policy and procedures relating to Staff Training and Competency are defined in the Departmental Training Policy – [**MP-CGEN-019**]. |
|  | **Management Systems** | Facilitated by Q-Pulse, the Department operates a Clyde-wide Quality Management System (QMS) database – policies and procedures for this are defined in – [**MP-CGEN-002**]**.** The Quality Manager has defined responsibilities for the maintenance and administration of this QMS.General management functions of NHSGGC, inclusive of all NHSGGC Policy Documents, are accessed by all staff via StaffNet (NHSGGC Intranet). |
| **The repertoire of testing on each site** | The Departmental Testing Repertoire is defined in Section 2.1.4 of this Manual. |
| **The calibration of equipment** | See also – Section 17.3 of this Manual. Clyde-wide policy and procedures for the calibration of equipment is defined in [**MP-CGEN-012**]. |
| **The transfer of samples between locations** | NHSGGC Policy is defined in the NHSGGC Specimen Policy. For the Department, Clyde-wide policies and procedures inclusive of specimen transport, by hospital staff, contracted couriers and taxis, are defined in [**LP-CBSC-003**] – this document also includes details for sending and receiving samples via post. Procedures specific to blood transfusion are defined in [**LP-CBTR-012**]**.** |
| **The movement of technical staff** | The Department Management Team have cross site (Clyde-wide) responsibility. Technical staff are based at RAH but are trained to work during core hours across the Clyde Sector. Hospital Site specific shift rotas operate out with core hours and are staffed by dedicated out of hours teams familiar with the specific operation of each site. |
| **Laboratory Analytical Equipment** | See also – Section 17 of this Manual. The Department, where feasible, and financially prudent, facilitates identical equipment, reagents, reagent batches, and test kits, across the Clyde Sector. Section 2.1.4 identifies where analytical testing differs across the Sector. [**MP-CGEN-010**]defines Clyde-wide policy and procedures relating to the Management of Equipment, with [**MP-CGEN-011**] defining policy and procedures relating to Reagents, Calibration and Quality Control Materials. |
| **Laboratory Reporting arrangements** | See also – Section 21 of this Manual. Reporting arrangements, for each Examination Procedure, are defined as part of the Examination Procedure SOP.In addition, as managed and facilitated by the Department of HIT, NHSGGC operates NHSGGC-wide using standardised / common IT Systems, that include:- Telepath Laboratory Information Systems covering all Diagnostic Laboratories,- Electronic Test Requesting & Reporting Systems, inclusive of TrackCare, SCIStore and Clinical Portal, ICE (GP Order Comms). |
|  | **Define procedures to ensure that enquiries about work in progress are handled efficiently, regardless of any transfer between locations.** | Clyde-wide policy and procedures relating to the telephoning and the logging of calls are defined in **–** [**LP-CGEN-005**].NHSGGC operates a NHSGGC-wide LIMS system which allows access from any site.Specimen transport systems use dedicated coloured transport bags to direct primary care samples throughout Clyde in an appropriate manner including urgency of request. A dedicated transport delivery system with runs 24/7 is defined within [**LP-CBSC-003**]**.** |
|  | **Ensure that reviews of requests, tenders and contracts include appropriate consideration of clients’ awareness of the way the organisation operates across the various locations.** | The Department conducts periodic user surveys, and the senior technical managers conduct site visits when required, to evaluate and manage service delivery issues. The Department also submits a quarterly newsletter to primary care staff, to communicate service change and development. StaffNet (NHSGGC Intranet) serves to provide a similar function for secondary care staff.Step one of the Managed Service Contract (MSC), (see also Section 17.1.2 of this Manual) represents a technical specification, prepared consistent with user requirements, for the service. A Managed Service Staff Group meets regularly to evaluate and address service requirements and to progress outstanding issues. SLA’s (as defined in [**MP-CGEN-013**] are reviewed, as a minimum, on an annual basis.  |
|  | **Have mechanisms in place to ensure that enquiries about work in progress are handled efficiently, regardless of any transfer between locations.** | NHSGGC IT systems, e.g. Telepath LIMS and TrackCare facilitate full audit trail of sample status. Primary Care staff, as facilitated by the User Handbook, and also, an NHSGGC-wide telephone contact list [**MF-CGEN-022**],operate to communicate 24/7 access for advice and results interpretation.Clyde-wide procedures operate for incident reporting and management [**MP-CGEN-005**] include the reporting of Analyser / Service Delay / Down Time, and Complaints. |

# 14.0 Management Review (ISO 4.1.2.1, ISO 4.15)

In addition to process review, as routinely undertaken by Management Committees and Meetings - see Section 3.7.5, the Departmental Management Team coordinates formal Annual Management Review. This meeting is conducted using a defined protocol [MP-CGEN-015], and standing agenda.

# 15.0 TECHNICAL REQUIREMENTS (ISO 5.1)

Accreditation systems stipulate requirements as to policies and procedures for personnel management, inclusive of:

## 15.1 Staffing & Personnel Qualifications & Job Descriptions (ISO 5.1.2, 5.1.3)

Assessment and review of the Departmental Staffing Plan (or Man-Power Plan, see Section 2.4.5.4) is regularly undertaken, both as on-going routine Departmental Management Team activity, and, as a standing element of the Annual Management Review Meeting [[**MP-CGEN-0**](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-013.AnnualManagementReview.doc)**15**].

## Medical Staff (See also Section 2.3)

As further defined in [MP-CGEN-020]:

* The Clyde Sector Lead Clinician (Laboratory Director) has nominated responsibility for the professional direction of the Department and for the delegation of clinical, scientific, professional, consultative, advisory, organisational, administrative and educational activities to Departmental staff, as appropriate.
* A **Consultant Haematologist** (**Site Lead Clinician**) professionally directs each Haematology / Blood Transfusion Laboratory, operating within the Clyde Sector, NHSGGC.

Consultant Job Descriptions / Job Plans include reference to:

* ***duties of the laboratory director or designee(s)***
* ***the laboratory director, or designee, to indicate competence and responsibility for the services provided,***
* Each consultant is professionally responsible and managerially accountable to the **Sector Lead Clinician**, who is professionally responsible and managerially accountable to the **Head of Service**.

Medical Staff Qualifications are defined in [MP-CGEN-020].

The Department, in conjunction with the West of Scotland Deanery, has responsibility for the training of and regular formal appraisal of Senior House Officers and Specialist Registrars in Haematology.

A Specialist Registrar and Senior House Officer rotation, for the training of medical staff, operates within the Department. Details of this rotation are held by the Clinical Director and Hospital Site Consultant Staff. Details regarding qualifications and necessary registrations are held by the Department of Human Resources, NHS Greater Glasgow.

Evidence of training, for consultant medical staff, is exemplified by membership or fellowship status of the Royal College of Pathologists, or equivalent, and entry to the General Medical Council (GMC) Specialist Register – see [**MP-CGEN-020].**

Each consultant has responsibility for maintaining CPD activity and its recording using a dedicated CPD activity folder, with compliance, and job description / job plan monitored at annual appraisal.

## Biomedical Scientific Staff

As further defined in [MP-CGEN-020], the Technical Services Manager is professionally responsible and managerially accountable to the Sector Lead Clinician, and to the General Manager, Diagnostics Directorate, NHSGGC.

Scientific Staff working within the Department are fully registered with the Healthcare Professions Council (HCPC). As legislated, Biomedical and Clinical Scientific Staff are required to update HCPC registration on an annual basis. The Technical Services Manager, ensuring compliance, is required to assure registration for Scientific Staff.

Qualifications and Job Descriptions of Biomedical Scientific Staff are held as part of Personnel Records by the Technical Services Manager. Additionally, staff qualifications, together with training records, are maintained by the Training Manager, using the Q-Pulse Staff & Training Modules.

## Healthcare Support Staff

Departmental Healthcare Support Workers (formerly Medical Laboratory Assistants, or MLA’s) work under supervision of Biomedical Scientist Staff. Though not required to be formally qualified, nor formally registered, Healthcare Support Staff are subject to comprehensive in-service training.

Qualifications and Job Descriptions of Biomedical Scientific Staff are held as part of Personnel Records by the Technical Services Manager.

## Administrative and Clerical Staff

Administrative and Clerical Staff (A&C) provide secretarial services. The administration, inclusive of NHSGGC Human Resource, Personnel Policies and Procedures, etc, for A&C staff form a nominated responsibility of the NHSGGC, Regional Services Divisional Manager (see Section 2.4.5.3).

## 15.2 PERSONNEL MANAGEMENT (ISO 5.1)

## 15.2.1 Staff Recruitment and Selection

The Department of Human Resources, NHSGGC, operates a systematic process for the recruitment and selection of staff. This process is subject to a number of defined policies and procedures within staffnet.

Copies of the above documents are accessed via StaffNet (NHSGGC Intranet) – see <http://www.staffnet.ggc.scot.nhs.uk/Human%20Resources/Resourcing%20Recruitment%20and%20Workforce%20Planning/Recruitment/Pages/default.aspx>

## 15.2.2 NHSGGC Staff Induction & Orientation (ISO 5.1.4)

Consistent with NHSGGC Policy, and Quality Standards, the Department ensures that all staff participate in a staff induction programme.

NHSGGC facilitates a six step model for staff induction and orientation with this model outlining key elements and responsibilities involved in induction – accessed via StaffNet – see:

<http://www.staffnet.ggc.scot.nhs.uk/Human%20Resources/Learning%20and%20Education/Induction/Pages/default.aspx>

A major element of the induction program, is the delivery of statutory and mandatory information, followed by competency assessment of staff, with this program designed to demonstrate that new staff have established a necessary understanding of statutory and mandatory information.

The Department, as an adjunct to NHSGGC Induction program, utilises a “New Staff Orientation and Induction Form” [**MF-CGEN-024**] and a cross-site induction form if required [**MF-CGEN-031**].

## 15.3 Staff Training, Education, & Competency Assessment (ISO 5.1.5, 5.1.6)

This section should be read in conjunction with the Departmental Quality Policy [**MP-CGEN-007].**

As stipulated in the NHSGGC Staff Governance Policy:

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

NHSGGC is fully committed to the training and education, both at under- and post-graduate level, of its staff.

As defined in the Training Policy [**MP-CGEN-019**], the Department is committed to providing a service of the highest quality and shall provide staff with training in compliance with local and National legislation and guides, inclusive of professional and or regulatory requirements, as outlined within this document.

## Review of Staff Performance and CPD (ISO 5.1.7 and 5.1.8)

This is defined within [**MP-CGEN-019**] and uses the KSF programme available via staffnet:

[http://staffnet/Human+Resources/Learning+and+Education/The+Knowledge+and+Skills+Framework/default.htm](http://staffnet/Human%2BResources/Learning%2Band%2BEducation/The%2BKnowledge%2Band%2BSkills%2BFramework/default.htm)

## 15.5 Personnel Records (ISO 5.1.9)

NHSGGC HR Policy in relation to the requirement and administration of Staff, or Personnel Records, is accessed via StaffNet – see:

<http://www.staffnet.ggc.scot.nhs.uk/Human%20Resources/Policies/Pages/default.aspx>

In full compliance with NHSGGC Policy and Quality Standards:

Medical Staff Records (held by the Head of Department), and,

Laboratory staff records, consistent with data security and confidentiality legislation, are subject to controlled access (electronic password control, and or, locked filing cabinet) by nominated staff, namely the Technical Services Manager, the Laboratory Manager, Quality Manager, and nominated deputies.

# 16.0 Accommodation & Environmental Conditions (ISO 5.2)

## Note – [MI-CGEN-051] (LABS-036) - outlines additional UKAS policy and guidelines in relation to the Laboratory accommodation and Environment.

See also – [**MP-CGEN-023**] **–** Management Policy for Accommodation and the Environment.

## 16.1 Premises and Environment (ISO 5.2.1, 5.2.2, 5.2.6)

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 site, and were refurbished, with works completed in March, 2013, to facilitate a single “Blood Sciences Core Laboratory”, that has included the integration of the analytical platform of the departments of Clinical Chemistry and Haematology, using a robotic track (pre-analytical and sample transport) system.

The Laboratories of Vale of Leven Hospital are situated on the grounds of Vale of Leven District General Hospital, and were re-sited, in November 2011, to a fully refurbished Laboratory facility, that is shared with the Department of Clinical Chemistry.

## 16.1.1 Climate (ISO 5.2.6)

Laboratory Working Areas and Store Rooms are temperature-regulated using automated climate control systems and automated or semi-automated air conditioning devices. Maintenance of Climate Control Systems forms a responsibility of the Hospital Estates Managers.

## 16.1.2 Services – Gas, Electricity, Water Supplies, and Waste Systems

The maintenance of the electricity supply of Departmental “essential services laboratories”, including all Clyde Sector Haematology and Blood Bank laboratories, is assured through emergency electricity back-up generator supply, which in the event of power failure, shall result in the restoration of power within 15 seconds. In addition, essential laboratory equipment, e.g. main analysers, blood and blood product storage equipment, LIMS, etc, are protected by no-break electrical protection systems (UPS). There is no gas provision. Maintenance of “Service Provision” (gas, electricity, water and waste services) form a responsibility of the Hospital Estates Managers.

## 16.1.3 Cleaning and Housekeeping

Hospital Managers are responsible, in conjunction with Hospital Domestic Supervisors, for the management of departmental cleaning protocols and work instructions. Administration, including audit of the effectiveness of the cleaning schedule, is the responsibility of the Domestic Supervisors.

In addition to this, the Department QMS includes procedures for the maintenance, cleaning and general housekeeping of laboratory equipment. Departmental staff are required to ensure that working areas are kept clean, tidy and uncluttered, and to maintain good housekeeping throughout the laboratory at all times.

## 16.2 Health & Safety (ISO 5.2.1, 5.2.2, 5.2.6)

NHSGGC Health and Safety Policy & Procedures, consistent with National Legislature, and Quality Standards, are accessed via StaffNet - <http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/Health%20and%20Safety/Pages/default.aspx> -

In compliance with NHSGGC Health & Safety Policies and procedures, the organisation and management of Health and Safety in each department is detailed in the Departmental Health & Safety Code of Practice [HP-CGEN-001], inclusive of:

## 16.2.1 Health & Safety Audit (ISO 5.2.1, 5.2.2, 5.2.6)

Departmental accommodation and facilities are subject to regular inspection and safety audit, performed by Departmental Staff and by Divisional Risk Managers and Fire Safety Officers. In addition, as stipulated by NHSGGC Policy, the Department is required to facilitate a program of Health & Safety Audit, inclusive of Fire Safety, Workplace and annual compliance assessment. This is facilitated using the Q-Pulse Audit Module. Annual Health & Safety compliance audit (Health & Safety Control Book) of the Department is also performed by NHSGGC Risk Management Staff.

## 16.2.2 Fire Safety

Managed, maintained and controlled by the Hospital Managers, in accordance with Fire Safety Legislation, appropriate numbers of Fire Alarm Breakpoints, Fire Extinguishers and Fire Blankets are located throughout the Department. In addition, smoke and / or heat-sensing alarms, which would be activated automatically in the event of a fire, are ceiling mounted at various points of the Department. Fire exits are provided for all areas, and are clearly identified.

The Departmental Health and Safety Code of Practice [**HP-CGEN-001**], made available to all staff at Departmental Induction, provides information for staff in all aspects of Fire Safety.

## 16.3 Facilities for Storage (ISO 5.2.3)

: This is how we do it.

* The integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.
* Clinical samples and materials used in examination processes must be stored in a manner to prevent cross contamination.
* Storage and disposal facilities for dangerous materials must be appropriate to the hazards of the materials and as specified by applicable requirements.

The department facilitates separate storage facilities for:

* Process and Quality Records – see [[**MP-CGEN-003**](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)],
* Clinical Material – defined in Examination Procedures and by [[[**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)](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)],
* Hazardous Substances [**HP-CGEN-001**],
* Reagents (including Calibration and Control Material) [[**MP-CGEN-011**](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-011.ReagentCalibration&QCMaterial.doc)].
* Blood and Blood Components (**BSQR**) [**MP-CGEN-018**] – see also, Section 16.3.1.

### 16.3.1 Store Rooms

Departmental Store Rooms, used for the storage of all non-refrigerated supplies, including laboratory consumables, reagents, and other goods, to assure satisfactory storage of goods, consistent with manufacturer requirements, are subject to continual temperature monitoring. In addition, periodic and annual audit, e.g. Workplace Health & Safety Audit, serves to monitor departmental Store Rooms, consistent with Health and Safety legislation.

### 16.3.2 Staff Facilities (ISO 5.2.4)

There are wash facilities, clean drinking water, kitchens and lockers available for staff on all sites.

## 16.4 Facilities for Patients (ISO 5.2.5)

The policy of the Department of Haematology is that laboratory areas are restricted to authorised personnel. In consequence, patients are not permitted access to the laboratories. Facilities for patient consultation, specimen collection, and Point of Care Analyses, are provided within appropriate Hospital Out-Patient Clinic and Ward Areas, to include:

* A waiting / reception area with suitable facilities and access for disabled persons, inclusive of notices, to alert patients and visitors of potential Health and Safety hazards.
* Consultation and phlebotomy areas (to also accommodate parent / guardian / interpreter, as required) that facilitate appropriate privacy and recovery facilities, inclusive of First Aid Materials.
* Phlebotomy (and specimen collection areas) that enable specimen collection to be undertaken in a manner that does not invalidate results, or adversely affect the quality of the Examination.
* Toilet facilities for patients separate from those provided for staff.

# 17.0 Laboratory Equipment, Reagents & Consumables (ISO 5.3)

**Definitions (ISO 5.3):**

* Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems.
* Reagents include reference materials, calibrators and quality control materials;
* Consumables include culture media, pipette tips, glass slides, etc.

### Procurement of Equipment (GMP, ISO 5.3.1)

Consistent with ISO 15189, [**MP-CGEN-010**] serves to define procedures for the selection, purchasing and management of laboratory equipment, inclusive of:

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

The Management Policy “Change Control & Validation” [**MP-CGEN-008**]serves to define 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).

### GMP Guide – Procurement of IT Equipment (GMP - Annex 11)

The GMP Guide - Annex 11 [**MI-CGEN-017]** specifies requirements, management protocols, inclusive of selection and procurement principles, specifically applicable to computerised systems used in the Blood Transfusion Laboratory (termed as “GMP regulated activities”) (also see Section 22.0).

### 17.1.2 NHSGGC - Managed Service Contract

As further defined in [**MP-CGEN-010**], 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.

Details specific to the Equipment Tender Specification (URS) are defined in [**MF-CGEN-013**], with the Scoring Matrix (to facilitate “Tender Assessment”) detailed in [**MF-CGEN-014**].

### Equipment Acceptance Testing (ISO 5.3.1.2, 5.5.1)

As defined by ISO 15189, the Department is required to verify, upon installation, and before routine use, that the equipment is capable of achieving the necessary performance, pre-determined by the URS to assure compliance with requirements in relation to associated Examination Procedures.

As further defined in [**MP-CGEN-010**], and prior to formal acceptance, or “handover”, of new equipment from any supplier, the department is required to assure:

* Equipment must be validated in accordance with Policy and Procedures relating to Change Control & Validation [**MP-CGEN-008**] **PRIOR** to installation into routine laboratory use.

### Calibration & Metrological Traceability (BSQR, GMP, ISO 5.3.1.4)

GMP Guide - Annex 17 [**MI-CGEN-059**] andUKAS Technical Position Statement– 41 (**TPS - 41**) [**MI-CGEN-052**], defines procedures for calibration and metrological traceability.

TPS-41 also 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 (**ISO 5.3.1.4**), 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, but the acceptable accuracy will not be more than +/- 1%. |

### Equipment Maintenance and Repair (BSQR, ISO 4.10, 5.3.1.5)

The department operates a systematic program [**MP-CGEN-010**] of equipment maintenance that ensures equipment is used, maintained, serviced, decontaminated and calibrated (where appropriate) in accordance with written Manufacturer and Departmental Policies and Procedures, and that equipment is operating within a written manufacturer’s specification, and or working to a defined performance evaluated and defined by validation of the device.

For maintenance works performed by external maintenance / service engineers, it is important that department staff are informed of the nature of works to be performed, and that the engineer has been informed of hazards relating to maintenance work required. This process is facilitated by a **Permit to Work Form** [**MF-CGEN-005**], completed **PRIOR** to maintenance / service work being performed.

### Maintenance Contracts

The Technical Services Manager, in conjunction with the General Manager, Diagnostics Directorate, NHSGGC, and the Supplies & Purchasing Department, NHSGGC, is responsible for the administration of maintenance and or service contracts.

### Maintenance Contracts – IT and Computerised Systems

IT equipment is managed, in all aspects, by the Department of E-health, NHSGGC. Where appropriate, contract details serve to define roles and responsibilities of staff where the contract with an outside contractor is operational, e.g. NHSGGC Managed Service Contract with Abbott.

### Maintenance Contracts – GMP Critical Blood Bank Equipment (BSQR)

With requirements further defined in [**MP-CGEN-018**]**,** Blood and Blood Product Storage Cabinets (including fridges, freezers, platelet incubators and plasma thawing devices) utilised by the department, are specifically maintained via a service contract. This contract includes calibration of temperature provision, temperature mapping, and calibration and testing of temperature monitoring devices and associated alarm systems.

Consistent with maintenance requirements, the Diagnostics Directorate, NHSGGC is contracted with C&M Scientific Ltd for the maintenance and service, inclusive of temperature mapping, alarm and refrigeration systems calibration testing, consistent with the requirements of the BSQR, for Blood and Blood Component Storage Cabinets (classed as GMP Critical Equipment). Requirements are further defined in [**MF-CGEN-006**] **-** Validation Master Plan.

### Maintenance Contracts – Satellite Blood Fridges (BSQR)

In compliance with the BSQR [**MI-CGEN-064**], the contracting of maintenance requirements and the management of Satellite Blood Fridges at the Cowal Community Hospital, Dunoon, and the Victoria Hospital, Rothesay, forms a responsibility of NHS Highland.

Consistent with NHSGGC requirements, as further defined by SLA (see following), this contract, held with C&M Scientific Ltd, includes routine maintenance and thermal mapping monitoring.

* [**SC-IBTR-001**] defines management requirements and associated responsibilities, for the Satellite Blood Fridge, facilitated at the Cowal Community Hospital, Dunoon.
* [**SC-IBTR-002**] defines management requirements and associated responsibilities, for the Satellite Blood Fridge, facilitated at the Victoria Hospital, Rothesay.

### Equipment Adverse Incident Reporting (BSQR, GMP, ISO 5.3.1.7, 5.3.2.6)

GMP Guide - Annex 20 [**MI-CGEN-058**] stipulates requirements for Quality Risk Management. It includes principles to be used and options for processes, methods and tools which may be used when applying a formal quality risk management approach.

### 17.5.1 Definition of Quality Deviation

As further defined in [**MP-CGEN-005**] the department defines Quality Risk Management as a systematic process for the assessment, control, communication and review of risks to the quality of the laboratory service. A deviation is defined as a “departure from standard procedures or specifications resulting in non-conforming material and/or processes or where there have been unusual or unexplained events which have the potential to impact on service quality, system integrity or personal safety”.

### Incidents Involving Blood or Blood Products (BSQR, GMP, ISO 5.3.1.7)

The BQSR [**MP-CGEN-018**] stipulates requirements for the reporting of incidents involving Blood and Blood Products. The following guidance (further detailed in [**MP-CGEN-005**] should be read in conjunction with:

1. Recall of Blood & Blood Components [**LP-CBTR-001**]and [**LF-CBTR-001**], and,
2. Investigation of a Suspected Transfusion Reaction [**LP-CBTR-002**], [**LF-CBTR-003**]**,** & [**LP-CBTR-004**],
3. **SABRE** reportable incidents should be ‘notified’ to **SABRE** as soon as practical [ideally within 1-2 working days of identification of the incident].
4. It is the responsibility of Blood Bank Staff to ensure initial notification of an incident using **DATIX**, and to consider incidents for reporting to **SHOT / SABRE**.
5. Cases involving suspected Transfusion Transmitted Infections, or potentially severe complications of transfusion, shall also be notified to Consultant Haematology staff at the earliest opportunity.
6. The Transfusion Practitioner(s) shall investigate and review incidents and, in conjunction with Blood Bank staff, evaluate appropriate reporting procedures (including **SABRE** and **SHOT**).

### Equipment Records (ISO 5.3.1.7)

### 17.6.1 Laboratory Equipment Inventory

As further defined in [**MP-CGEN-010**], and facilitated by the Q-Pulse Equipment Module, the departmental Equipment Inventory forms the starting point for necessary documentation and records in the effective management of equipment. The purpose of the equipment inventory is to enable, and facilitate, the following information:

* To enable traceability audit of equipment use,
* To facilitate maintenance and servicing contract scheduling and reports recording, including calibration reports, temperature mapping reports for blood storage cabinets, etc
* To assist in equipment replacement planning.

### Maintenance Records

Laboratory work instructions relating to operator (ordinarily departmental Staff) preventative maintenance, are prepared for all laboratory equipment, and serve to ensure laboratory equipment is maintained to optimum performance levels. Such Work Instructions are defined:

a) **For Main Analysers** – Examination Procedures include a section, specific to maintenance requirements, inclusive of scheduled operator maintenance, and also, maintenance procedures as contracted to an external maintenance / service engineer. For main analysers, on-board systems are routinely used to record, or log, maintenance procedures performed.

b) **For general laboratory equipment**, e.g. cleaning of fridges, benches, centrifuges, etc - standalone Laboratory Work Instructions serve to define maintenance tasks. In addition, Laboratory Forms, in the form of Maintenance Logs, are identified by the procedure document, and serve to record the satisfactory completion of maintenance tasks.

### Contracted Maintenance / Service Reports

Maintenance / Service / Calibration Reports, ordinarily provided by a Maintenance / Service Engineer on the completion of works, serve to define and record equipment maintenance, including what work was performed, who did the work, and when the work was performed. Work related problems identified by the engineer will also be recorded using this report.

### Reagents and Consumables (ISO 5.3.2)

As further defined in [**MP-CGEN-011**], and in compliance with ISO (**ISO 5.3.2.1**), the Department operates procedures for the reception, storage, acceptance testing, and inventory management for Laboratory Reagents, and Consumables.

### Reception and Storage (ISO 5.3.2.2)

Consistent with NHSGGC Policy for the receipt of goods (Standing Financial Instruction No.9), as further defined in [**MP-CGEN-011**], on delivery of goods, usually to laboratory Reception areas, and prior to receipt verification (when appropriate).

### Acceptance Testing (Batch Testing) (BSQR, GMP, ISO 5.3.2.3)

Departmental procedures for “Batch Acceptance Testing” and “batch comparability and acceptance”, inclusive of “Quarantine” requirements, are defined in [**LP-CGEN-012**], whereas, [**LP-CBTR-006**] defines procedures specific to Blood Bank Stock Management, inclusive of batch acceptance criteria and procedures.

### Inventory Management (Stock Management) (ISO 5.3.2.4, 5.3.2.5, 5.3.2.7)

As further defined in [**MP-CGEN-011**], Departmental stock management procedures serve to assure:

* Stock is appropriately stored, at all times, to manufacturer / supplier specification,
* Stock is stored (inclusive of appropriate stock rotation) in a way that ensures staff use only goods within expiry date, and that expired goods are appropriately disposed.

Details relating to the storage and stock management of reagents, calibration and quality control materials, inclusive of instructions for the use, inclusive of preparation are defined within individual Examination Procedures.

To facilitate stock management requirements, the department uses a software-based Reagent Management System (RMS). Using Departmental PC’s and hand-held electronic data scanners, this system facilitates electronic stock data entry, number /volume of goods, their lot and expiry data and, date of receipt. Stock on receipt, and post data entry to the system, is subsequently bar-coded, and “booked out” by the user when put into operational use using the data scanners. Procedural Information for the use of the RMS System is detailed in [**LP-CGEN-003**]**.**

### Reagents and Consumables – Instructions for Use (ISO 5.3.2.5)

Instructions for the use of reagents and consumables are defined in SOP’s (Examination and Laboratory Procedures)

### Reagents and Consumables – Adverse Incident Reporting (ISO 5.3.2.6)

Procedures for the reporting of adverse incidents attributed to reagents and or consumables are defined in Section 17.5

### Safe Disposal of Material

Departmental procedures for the disposal of laboratory waste, including reagents and consumables, calibration and Quality Control Material, are defined in [[**HP-CGEN-002**](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\LWI-ALL-ALL-006.WasteDisposalProcedures.doc)] , in COSHH Risk Assessments (included with SOP’s), and in the Health & Safety Code of Practice [[**HP-CGEN-001**](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\LWI-ALL-ALL-006.WasteDisposalProcedures.doc)]

# 18.0 PRE-EXAMINATION PROCESS (ISO 5.4)

Departmental policy and procedures in relation to the pre-examination phase are further defined in [**MP-CGEN-016**]. In addition, a process flowchart is used to further define the pre-analytical phase, specific to the Blood Transfusion Laboratories [**LI-CBTR-010**].

### Information for Users and Patients (ISO 5.4.2)

Information for Service Users is provided in the form of a Service User Handbook: [**MF-CGEN-022**] **–** Department of Haematology, Clyde Sector – Service User Handbook, with access to users via StaffNet –

<http://www.staffnet.ggc.scot.nhs.uk/Acute/Diagnostics/All%20Laboratory%20Medicine/Clyde%20Laboratory%20Medicine/Pages/LM_LaboratoryManuals_AL_180308.aspx>

A number of Patient Information Leaflets, supplied by the appropriate hospital directorate or service, are routinely issued to patients prior to any medical or surgical intervention being performed, e.g. mailed to patients together with consultation / appointment details. The Management Policy for Specimen Collection [**LP-CBSC-002**], prepared as an adjunct to the NHSGGC Specimen Policy (accessed via StaffNet) includes patient information leaflets for: a) Having a Blood Test; b) Information for Patients having a Bone Marrow Biopsy Procedure.

### Request Form (ISO 5.4.3, 4.4.1)

The department’s of Clinical Chemistry, and Haematology, Clyde Sector, NHSGGC, co-facilitate the use of a TrackCare (electronically) generated Specimen Request, inclusive of a Laboratory Request Form, with appended sealable specimen bag, or a hard-copy, or paper equivalent. A separate Request Form with specimen bag is used to facilitate Blood Transfusion Requests.

As further defined in [**MP-CGEN-016**], on receipt by the Department, requests ***accepted*** by the Department for examination(s) shall be considered as a contract or “agreement”, between the test requestor, and the Department (as stipulated by **ISO 4.4.1**). Subsequent to acceptance, the Request Form serves to facilitate Patient Identification and Laboratory Number Data entry to the laboratory computer system (LIMS). Subsequent to data entry, Request Forms are scanned [**LI-CGEN-003**] to facilitate electronic request data storage.

Required information for the completion of request forms, inclusive of minimum acceptance (and rejection) criteria, the ordering of laboratory tests, and or services, is detailed in Service User Handbooks, as defined in Section 18.1.

### Specimen Collection and Handling (ISO 5.4.4)

The General Manager, Diagnostics, NHSGGC, is nominally responsible for the implementation and maintenance of systems for laboratory specimen collection, inclusive of the training and management of clinical staff, including Phlebotomy Staff, responsible for specimen collection (Laboratory Staff are NOT directly responsible for Specimen Collection).

NHSGGC Specimen Policy, and, Specimen Collection (inclusive of Phlebotomy) Procedures[**LP-CBSC-002**] serve 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).

### Specimen Transportation (ISO 5.4.5)

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 Service User Handbooks (see Section 18.1).

Specimen transport arrangements are defined in[**LP-CBSC-003**], which serves to define procedures and guidelines relating to the safe transport and distribution of laboratory specimens destined for analysis by the Departments of Clinical Chemistry and Haematology (Blood Sciences), Clyde Sector, NHSGGC.

### [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.

### [Specimen Reception](#INDEX) Procedures (BSQR, ISO 5.4.6, 5.4.7)

[**LP-CBSC-001**] serves to define procedures and guidelines relating to the safe and appropriate acceptance (and rejection) of laboratory specimens destined for analysis by the Departments of Clinical Chemistry and Haematology (Blood Sciences), Clyde Sector, NHSGGC, and is applicable to all Clyde Sector; Blood Sciences Staff (Clinical Chemistry and Haematology.

**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.

Consistent with ISO (**ISO 5.4.7**) requirements, Examination Procedures detail procedures for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage. In addition, procedures detail specimen viability (life-time) limits for requesting additional examinations or further examinations on the same primary sample.

# 19.0 Examination Processes (ISO 5.5)

Departmental policy and procedures in relation to the examination phase are further defined in [**MP-CGEN-016**]. In addition, a process flowchart is used to further define the analytical phase (Examination Processes) and laboratory service, specific to the Blood Transfusion Laboratories [**LI-CBTR-011**].

### Selection, and Validation of Examination Procedures (ISO 5.5.1.2)

The Departmental Change Control & Validation Policy (and associated procedures) serves to define procedures and requirements for Change Control, and also, the evaluation and performance of validation (and verification) of process change. Elements include:

### Change Control (BSQR, GMP)

As further defined by the BSQR [**MI-CGEN-064**] and[**MP-CGEN-018**] the purpose of change control is to provide a systematic method for assessing the impact of change on any activity which might have an effect on the safety and / or quality of Blood & Blood Products, components or services (specific regulatory requirements are detailed in Annex 15 of the GMP Guide [**MI-CGEN-057**]).

As further defined in [**MP-CGEN-008**], and using a dedicated Form ([**MF-CGEN-007**], (for IT Equipment, [**MF-CGEN-008**]) the Departmental Change Control Policy applies to Departmental activities assessed to have an impact, or potential impact, on the quality and / or safety of the laboratory service. This policy also applies to the installation and upgrading of equipment and services, including projects managed by external organisations.

### Validation & Verification (BSQR, GMP, ISO 5.5.1.2, 5.5.1.3)

The departmental processes relating to the Validation (and verification) of Examinations, is further defined by the following:

### Validation Policy

The Validation Policy [**MP-CGEN-008**] serves as a strategy document to define the validation process and its purpose within the Department, and makes a commitment to maintaining critical processes and systems in a valid state, consistent with Quality Standards and guidelines. The Validation Policy specifies what should be validated and how validation is executed, when review and or re-validation is required, with maintenance of the validated state defined in the **Validation Master Plan**.

### Validation Master Plan (VMP)

The VMP [**MF-CGEN-006**] details critical processes, equipment, facilities and systems, and procedures for recording when they were last validated and when re-validation is due. The VMP is the operational document which allows the laboratory to turn the Validation Policy into practice and provides a route map to how the laboratory ensures critical processes and systems remain valid and fit for purpose throughout their life-cycle from initial procurement, installation and routine operation to withdrawal, or replacement.

Requirements for the validation of Examination Process, inclusive of the approach towards evaluation, statistical analysis, measurements of precision and accuracy, etc, are further defined in [**MP-CGEN-021**].

### Validation Report Form

**Validation Summary Report** [**MF-CGEN-008**] serves to define:

* + The **Validation Protocol,** inclusive of: how qualification or verification (Installation, Operational and Performance) will be performed, the review and approval of key stages; and, the identification of critical steps (including Risk Assessment, where appropriate) and acceptance criteria, defines how validation of equipment, facilities and systems or process will be conducted.
	+ The outcome of the validation process, inclusive of the assessment of “fitness for purpose”, and hence, the authorisation for the introduction to operational use.

### Measurement Uncertainty of Measured Quantity Values (ISO 5.5.1.4)

In compliance with ISO (**ISO 5.5.1.4**), and as further defined in [**MP-CGEN-021**], the Department determines measurement uncertainty for each measurement procedure, as an element of the Examination Procedure SOP.

### Biological Reference Intervals & Clinical Decision Values (ISO 5.5.2)

In compliance with ISO (**ISO 5.5.2**), reference values for each Examination Procedure are:

* Printed on each laboratory report,
* Sourced within the Service User Handbook [**MF-CGEN-022**], as accessed via StaffNet.
* Defined in individual test Examination Procedures.

### Definition of Reference Values

As further defined in [**MP-CGEN-021**], Reference Values 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.

### Clinical Advice & Decision Values

During normal office hours, clinical advice and test results advice are available through contacting the laboratory. Contact information, inclusive of Haematology Medical Staff is communicated to Service Users via the Service User Handbook [**MF-CGEN-022**] as accessed via StaffNet.

### Documentation of Examination Procedures (ISO 5.5.3)

As further defined in [**MP-CGEN-002**], the department operates a systematic process to manage document control. Consistent with Document Control requirements, the department also acknowledges the importance of Standardised Operating Procedures in the provision of a quality diagnostic service.

Procedures (or Instructions, and often referred to as **SOP’s or standard operating procedures**) are defined as the way in which policy or policies are translated into action. In its most simple form a process is *what* needs to be done whereas a procedure is *how* something must be performed.

# 20.0 Assuring the Quality of Examinations (ISO 5.6)

### 20.1 Quality Assurance

As further defined in the Departmental Quality Assurance Policy [**MP-CGEN-017]**, and as directed by Quality Standards, the department operates an integrated approach to Quality Assurance.

### 20.2 Departmental Quality Control Policy & Procedures (ISO 5.6.2.2, 5.6.2.3)

As further defined in the Departmental Quality Assurance Policy [**MP-CGEN-017**], key elements relating to the performance and management of Quality Control are outlined.

### 20.3 External Quality Assessment (EQA) Policy & Procedures (ISO 5.6.3.1)

In addition to **ISO 5.6.3.1,** UKAS Technical Position Statement – 47 (**TPS-47**) defines UKAS Policy re- “Participation in Proficiency Testing”.

As further defined in the Departmental Quality Assurance Policy [**MP-CGEN-017**], key elements relating to EQA include:

In accordance with ISO, and the BSQR, the department shall:

1. Participate in External Quality Assessment Schemes, where available, corresponding to the repertoire of tests.

Where there is no EQA scheme available (**ISO 5.6.3.2**), the department is required to facilitate an “*alternative approach*”. Procedural details are defined in Examination Procedures, and may include the testing of: as in TPS 47.

1. Operate standardised protocols (**ISO 5.6.3.3**) (defined in Examination Procedures) for the receipt, storage, analysis, data reporting, and data interpretation, including procedures for unsatisfactory analysis, for all EQA results. See also, Guidelines for the Analysis & Reporting of EQAS [**LP-CGEN-004**].
2. As a standing agenda item of the Departmental staff and Quality Team Meeting, formally review External Quality Assessment Scheme results (**ISO 5.6.3.4**). This process is facilitated by the Form [**QF-CGEN-016**].
3. **Error, e.g. Persistent unsatisfactory EQAS results**, or results that are **persistently out with consensus**, etc, shall be notified to the Quality Manager as a Quality Deviation, as defined in the Risk & Incident Management Policy [**MP-CGEN-005**].
4. Store EQAS reports in compliance with defined minimum retention criteria.

### 20.3 EQA Register

The departmental EQA Register [**QF-CGEN-017**]serves to define EQA schemes (including NEQAS) subscribed to by the department, inclusive of:

* EQA as subscribed
* Hospital Site / Laboratory Registration Details / Subscription Information,
* EQA Scheme Organiser,
* Participant (Hospital Site) Reference Number,
* EQA Scheme Details,
* Frequency of the EQA Scheme.

### 20.4 POCT EQA Register

Forming a mandatory requirement, as defined by ISO and NHSGGC POCT Policy, POCT Services supported by the Department are required, where available, to be registered with an External Quality Assurance Scheme provider.

[**QF-CGEN-018**] serves to define EQA schemes (including NEQAS) as subscribed to by the Department. This Register defines:

* EQA schemes as subscribed,
* POCT Device Registration / Subscription Information,
* EQA Scheme Organiser,
* POCT Device Location,
* Frequency of the EQA Scheme.

### 20.4 Comparability of Examination Results

 (**ISO 5.6.4**), as further defined in [**LP-CGEN-010**], the Department facilitates a program of 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**], the Department operates systems to document, record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be recorded as a Quality Deviation, acted upon and records of actions retained.

# 21.0 Post- Examination Processes (ISO 5.7, 5.8, 5.9)

Departmental policy and procedures in relation to the Post-Examination phase are further defined in [**MP-CGEN-022**].

### 21.1 Review of Results (ISO 5.7.1)

 (**ISO 5.7.1**), 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.

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.

### 21.2 Storage, Retention & Disposal of Clinical Samples (ISO 5.7.2)

[**MP-CGEN-003**] 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 Departmental Health & Safety Code of Practice [**HP-CGEN-001**], in Clinical Waste Procedures [**HP-CGEN-002**], and in NHSGGC Clinical Waste Procedures –

<http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/Health%20and%20Safety/Corporate%20Health%20and%20Safety/Documents/Policies/Waste%20Policy.pdf>

### 21.3 Reporting Results (ISO 5.8 & 5.9)

ISO identify the requirement for laboratories to produce results of examinations that are correct, timely, unambiguous and clinically useful.

For the department, analytical test results are authorised principally by trained and qualified Biomedical Scientist Staff, and also, by trained Haematology Medical Staff. The Laboratory Information System functions to store, and staff and authorised service users access to, validated laboratory results, or reports. Defined procedures for reporting of results are outlined within Examination Procedures. Examination Procedures, in this regard, contain detail as to:

* Procedures for Printed Reports and the Report Format,
* Procedures for entry of results to the LIS, and the electronic validation of results,
* Procedures for the reporting of abnormal results, including when, and to whom,
* Procedures for the electronic issue of reports,
* Procedures for Telephoned Reports,
* Turnaround Time for Examination Procedures,

Consistent with the Departmental Quality Policy, the department endeavours to issue reports of examinations, which are correct, timely, unambiguous and clinically useful.

### 21.4 Policy for Informing Service Users of UKAS Accreditation Status on Reports (URN BIS 16 25 and UKAS Lab 1 [MI-CGEN-044])

The Department, as further defined in **MP-CGEN-022 – Policy for 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 laboratories are a UKAS accredited laboratory (No 8046) for all tests with the exception of GFST“.***

Blood transfusion reports make no mention of UKAS accreditation, as per Lab 1 Section 5.1 we choose to inform our users of our accreditation status by including a link to the UKAS Schedule of Accreditation on the laboratory Intranet page and in the service users’ handbook.

 A table of tests is also included in the service users’ handbook which indicates the tests which are included in the laboratory accreditation scope.

### 21.5 TURNAROUND TIMES (ISO 4.14.7)

As defined in the Service User Handbook [**MF-CGEN-022**], the department is committed to the following:

* Turnaround Times for Examination Procedures are defined in the Service User Handbook, and in Examination Procedure documents.
* Results for "**EMERGENCY / URGENT FBC and COAGULATION SCREEN TEST requests**” will be reported and accessible **within 1 hour of receipt in the Laboratory**.
* **Routine** (or non-urgent) laboratory test requests will be reported on the same day of receipt.
* **NOTE – the requirement for a blood film examination (FBC), including the potential requirement of Haematology Medical Staff review (FBC and Coagulation Screen Tests), may delay reports beyond the stated TAT.**
* **“EMERGENCY”** **Cross-match** **and Blood Product requests** are dealt with as an immediate priority, with blood typically available within 50 minutes of the receipt of the sample in the transfusion laboratory.

When there are antibodies present or the patient has “special blood requirements”, the provision of cross-matched blood will take longer. In addition, delays in the provision of blood and or blood components is likely where there is a requirement to refer the specimen to the Scotland National Blood Transfusion Service (SNBTS), for further investigation, or cross-matching. Ward and or medical staff will be advised of any delay in cross-matching or the provision of blood products.

### 21.6 Reporting Results (ISO 5.9)

Hard copy (paper) reports, where requested by the Service User, are delivered using (meeting with data protection and confidentiality legislation) sealed opaque envelopes, to the delivery address stated on the test request form. As indicated, a number of Service Users opt to receive, consistent with NHSGGC cost reduction strategies, reports electronically via a secure EDT feed.

Electronic access to reports is limited to authorised staff and service users through unique user ID and password entry protection. This is further defined in the NHSGGC IT Security Policy –

<http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Health%20Information%20Technology/Infrastructure/ITsecurity/Pages/ITSecurity.aspx>

Telephoned reports, as shall be further defined, are reported only to qualified healthcare professionals, or to authorised recipients.

The Laboratory Information System (LIS) is utilised for the storage of all departmental test data, and the generation of all laboratory test reports. Procedural information, for both processes is detailed within the test Examination Procedure.

The department, facilitated through user audit and communication, is committed to the provision of clear, unambiguous reports that are designed to provide information of clinical value. Where relevant, reports are annotated to provide interpretative guidance, particularly where specialist investigations have been performed.

Laboratory reports are issued to users in electronic format (LIMS, EDT & SCI Store results access), and hard paper copy (unless suppression of a printed report has been requested by the user).

Consideration, including communication with and distribution of proof copies of proposed changes to both service users, and Medical Records Management, is given prior to issue of new or changed report forms.

### 21.6.1 Results Validation and Automated Reporting (ISO 5.9)

With regards to results validation, and also, automated results validation (and reporting), Examination Procedures define procedural instructions, 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.

### 21.6.2 Content of Printed Paper Reports (ISO 5.8.3)

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.

### 21.6.3 Content (Format) of ELECTRONIC Reports (ISO 5.8.3, 5.9.2)

The format of electronic reporting of test results is constantly reviewed in order to ensure compliance with service user requirements.

Following password controlled access, staff and service users, are able to access laboratory test data, including archived test data. The report format, from results enquiry screens, includes the following:

* 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.

### 21.6.4 Using SCI Store to Access Laboratory Results

The following Links are accessed via StaffNet:

* Accessing SCI Store - <https://ggc-scistore.scot.nhs.uk/Storeweb/Home/Login.aspx>
* SCI Store User Guides - <http://www.staffnet.ggc.scot.nhs.uk/Applications/SCI%20Store/Pages/SCI_Store_UserGuides_JB_190608.aspx>
* SCI Store Troubleshooting Guide - <http://www.staffnet.ggc.scot.nhs.uk/Applications/SCI%20Store/Pages/SCI_Store_FAQ_JB_180608.aspx>

### 21.6.5 Subcontracted Tests (ISO 4.5)

Departmental reports (on receipt of referred test results), in compliance with Quality Standards, 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.
* Where results from referral laboratories need to be transcribed, e.g. to the departmental LIMS, the Examination Procedure will include specific procedural instructions, including procedures for the verification of correct transcription.
* Where the referral laboratory issues a detailed and lengthy report an abbreviated version may be entered on the LIS, as long as the original full report is forwarded to the requesting clinician for filing in patient case notes. The LIS report should be identified as an abbreviated report.

### 21.6.6 The Telephoned Report

Departmental procedures (including the following information) relating to the telephoning and the logging of calls, are defined in[**LP-CGEN-005**]**.**

### 21.6.6.1 Telephone Call Logging (BSQR)

The logging of all telephone calls (message details & caller requirements) by the Hospital Blood Bank is identified as a requirement of the “Blood Safety & Quality Regulations”.

As defined by the Audit Checklist (OIG Website) -<http://www.transfusionguidelines.org.uk/index.aspx?pageid=1205&section=23&publication=REGS&Highlight=telephone;log>

Information to be logged includes the following:

* + Patient ID
	+ DOB
	+ Hospital number
	+ Message
	+ Caller ID
	+ Requirements
	+ Date and Time

In compliance of the above, departmental procedures relating to telephone calls, inclusive of the telephoning of laboratory results, or the recording of telephone requests, e.g. for laboratory tests, the requesting of blood and or blood products, and so on, are defined in[**LP-CGEN-005**]**.** In addition, a Laboratory Call Log Form [**LF-CGEN-004**] serves to log call details.

### 21.6.7 The Amended Report (ISO 5.9.3)

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**] 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.

### 21.7 Clinical Advice and Results Interpretation (ISO 4.7)

See Section 19.2.

# 22.0 Management of Data and Information (BSQR, ISO 5.10)

To facilitate access to laboratory data and information, consistent with the needs and requirements of the service user – see Section 13.2.

In addition, the department is required to facilitate procedures to assure compliance with Data Security and Patient Confidentiality (**ISO 5.10.2, 5.10.3**) – see Section 4.1.

### 22.1 Authorities & Responsibilities (ISO 5.10.2)

The authorities and responsibilities of personnel who use the Laboratory Information System (LIMS), including the maintenance and modification of this system, inclusive of:

a) Access to patient data and information;

b) The entry of patient data and examination results;

c) Those staff with responsibilities to change patient data or examination results;

d) Those staff with the authority to validate and report (release) examination results and reports are limited to HCPC registered Biomedical Scientists and Medical staff.

### 22.2 Change Control & Validation of Computer Systems (BSQR, GMP)

The **BSQR [MI-CGEN-064],** together with the **GMP** Guide - Annex 11 [**MI-CGEN-017],** specify key requirements, management protocols, inclusive of selection and procurement principles, specifically applicable to computerised systems used as part of a GMP regulated activities.

As further defined in [**MP-CGEN-008**], the Departmental Change Control Policy will apply to all departmental activities which have an impact, or potential impact, on the quality and / or safety of the laboratory service. This policy also applies to the installation and upgrading of equipment and services, including projects managed by external organisations.

Change control will be required prior to the introduction of all new or modified activities. This will include the following major activities:

* Test / Diagnostic Procedures (Examination Procedures),
* Computer Systems,
* Test equipment – analytical, and non-analytical equipment, where there is potential to impact on the quality of the service,
* Sample, and Blood / Blood Product Storage Devices (Fridges / Freezers / Plasma Thawer Devices / Platelet Incubators, etc),
* Sample and Blood & Blood Component Transport and Distribution (Cold Chain Management),
* Sample Reception / Book-in

The IT Department, NHSGGC, operates an independent Policy and Validation / Change Report Form, specific to the change / validation of IT Systems - see [**MF-CGEN-009**].