

Scottish Microbiology Reference Laboratories	MAN-QU-2 v 4
NHS Greater Glasgow and Clyde	Authoriser: Stephen Hughes
Issued: 17/08/2018	Author: Jane McOwan

Scottish Microbiology Reference Laboratories, Glasgow

Title: QUALITY MANUAL	
NUMBER / VERSION	MAN-QU-2 v 4
DATE OF ISSUE	17/08/2018
REVIEW INTERVAL	1 Year
AUTHORISED BY	S. Hughes
AUTHOR	J. McOwan
COPY 1	Master copy in Q-Pulse
LOCATION OF COPY	Refer to Master file in Q-Pulse

DOCUMENT REVIEW HISTORY	
All review / revision details are available in Q-Pulse	

Date	Amendment	Initials

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1.0 Introduction

The Scottish Microbiology Reference Laboratories, Glasgow are UKAS accredited to **ISO 1519:2012** - Reference number **8514**.

The full scope of accredited tests offered is available on the UKAS website <http://www.ukas.com>. Any tests reported by the laboratory which are NOT on this scope are clearly identified as such on the report; see also 5.8 reporting of results.

The laboratory has a quality management system in place to direct and control the laboratory with regard to quality. This system has established a quality policy and quality objectives and is designed to achieve those objectives. This is done through a process of quality planning which is the part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil quality objectives.

The Quality Management system ensures that:

- Laboratory management establishes written quality objectives, which are consistent with the quality policy and are regularly reviewed.
- This quality manual is reviewed at least annually, updated as required and any changes communicated to all personnel concerned.
- There is a quality manager who has responsibility for the implementation and maintenance of the quality management system.
- There is a process of document control.
- The control of process and quality records is according to current legislation, regulations and guidelines.
- The control of clinical material is according to current legislation, regulations and guidelines.
- Laboratory management conducts an annual review of the laboratory's quality management system and all its services.

This Quality Manual is cross-referenced to the procedures and forms used by the SMiRL, Glasgow.

The layout of this Quality Manual follows that of the **ISO 1519:2012** Standard for Medical Laboratories and is reviewed at the Annual Management Review.

In order to achieve an effective quality management system, there is a structure of documentation which covers all process undertaken by the laboratory.

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2.0 General information

The Scottish Microbiology Reference Laboratories, Glasgow are part of the Department of Laboratory Medicine within NHS Greater Glasgow and Clyde Health Board comprise of four areas of speciality:

1. Haemophilus, Legionella, Meningococcus and Pneumococcus
2. Parasitology
3. Salmonella, Shigella, Clostridium difficile and Screening of carbapenem resistant organisms (CRO) for carbapenemase genes using PCR
4. Methicillin Resistant Staphylococcus aureus

Address:

Level 5, New ListerBuilding
10-16 Alexandra Parade
Glasgow Royal Infirmary
Glasgow
G31 2ER

0141 201 8663

Information on the services provided and contact telephone numbers are available through the NHS Greater Glasgow & Clyde website:-

<http://www.nhsggc.org.uk/smrl>

Core Hours:

Weekdays
Monday – Friday 8.45 – 17.00

Weekends
Saturday 9am – 12.00pm
Sunday 9am – 11.00am

3.0 Introduction to the Quality Manual.

This Quality Manual describes the Quality Management System (QMS) of the SMiRLGlasgow. This manual fulfils two functions:

- It describes the QMS for the benefit of the laboratory's own management and staff
- It provides information for users and for inspection/accreditation bodies.

This Quality Manual may be regarded as the index volume to the management, laboratory, clinical and quality procedures. Subsequent sections of this Quality Manual are arranged so that they equate with sections of **ISO 15189:2012**. There is a brief description of the way in which the SMiRL, Glasgow seeks to comply with the particular section of the standard and references are given to appropriate procedures.

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The Quality Management System and the examination processes are continually evaluated and quality assured. 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.

The quality manual is reviewed on a yearly basis and knowledge of the quality manual is ensured by Q-Pulse e-mail document acknowledgement

4.0 Management requirements

4.1 Organisation and management responsibility

4.1.1 General

The organisation and management of the SMiRL, Glasgow is detailed in this manual. The laboratory accepts its responsibility to meet the requirements of **ISO 15189:2012** when carrying out work at its permanent facility at the New Lister Building, Glasgow Royal Infirmary.

4.1.1.2 Legal entity

The Scottish Microbiology Reference Laboratories, Glasgow are part of the acute services division of NHS Greater Glasgow & Clyde (GG&C) who are the organisation legally responsible. The Laboratory is encompassed under the Directorate of Clinical Microbiology, which offers diagnostic services and clinical liaison including infection control to NHS Greater Glasgow & Clyde and other Health Boards

ED-201 Clinical negligence and other risk indemnity

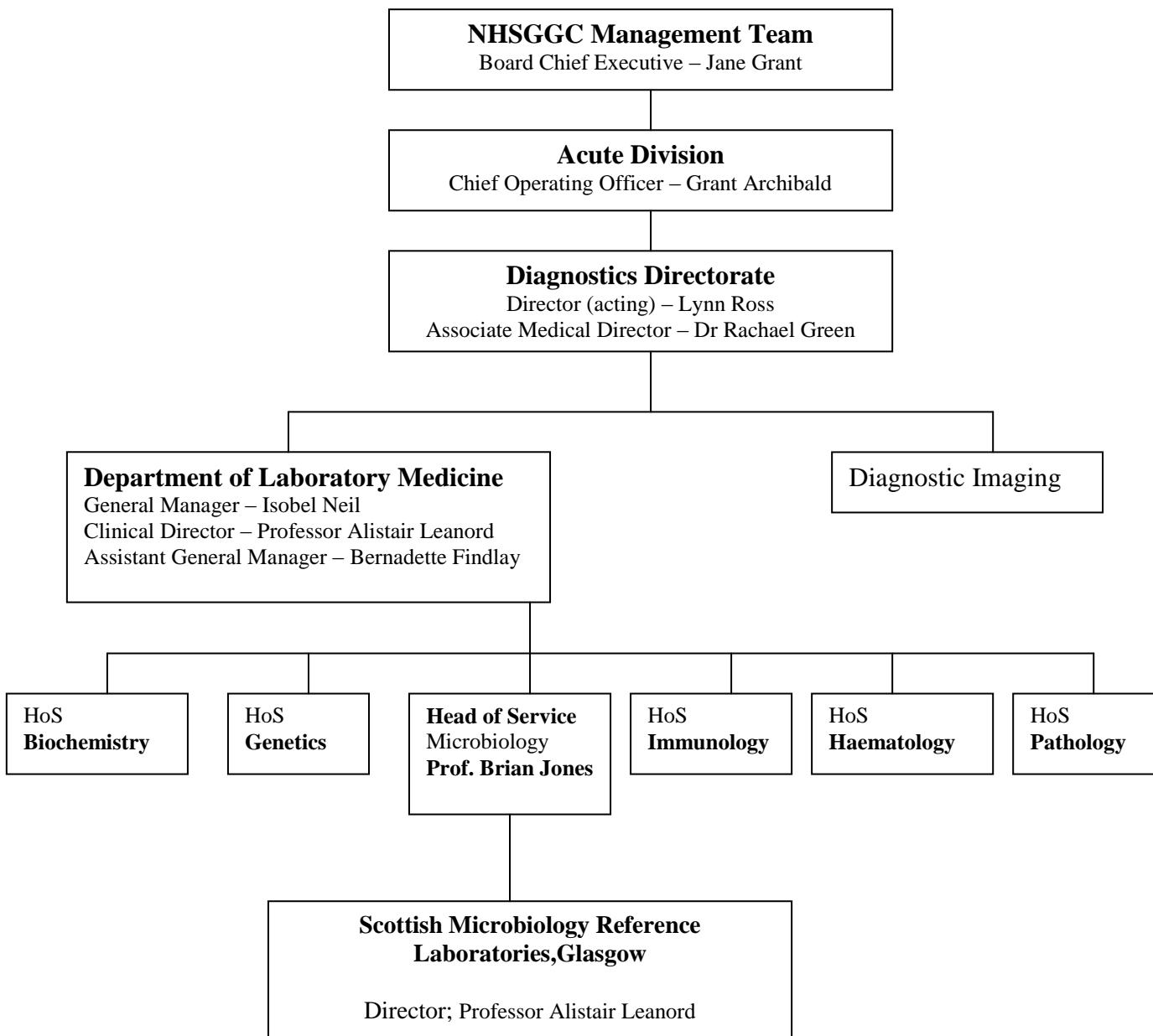
ED-202 CNORIS – Confirmation of Cover

Relationship to the Host Organisation

The Microbiology Management Team (MMT) NHS Greater Glasgow and Clyde consists of: Head of Service, General Manager, Assistant General Manager, Head of Department SMiRL, Glasgow, a Lead Clinicians from microbiology/virology laboratories in the north sector, the south sector, and Microbiology Technical Services Manager with the Virology/SMiRL, Glasgow Technical Services Manager.

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Microbiology, together with 5 other laboratory disciplines, is part of the Department of Laboratory Medicine. The Diagnostics Directorate is formed from Laboratory Medicine and Diagnostic Imaging.



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4.1.1.3 Ethical conduct

NHSGG&C Standing Financial Instructions and Fraud Policy [external documents ED-203 and ED-204 in Q-Pulse] ensure that work quality is not affected by external pressure, that users' confidential information is protected and that the department cannot undertake activity that would diminish confidence in its impartiality or operational integrity. Any potential conflicts of interest must be declared.

See Trust policies:

Register of Interests Policy

<http://www.staffnet.ggc.scot.nhs.uk/Applications/GAD/Pages/Summary.aspx>

Information Governance policy

<http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/PCHC/NHS%20GGC%20Clinical%20Governance%20Policy%20June%202016.pdf>

Conduct of individual staff is governed by their Contract of Employment, Professional bodies (General Medical Council, HCPC), Staff Code of Conduct, Standing Financial Instructions, Caldicott report & the Data Protection Act. Staff are made aware of this information at induction and it features as part of the Laboratory Generic Competence Record included in the Training Manual RL_TRM_2016.

Conduct of individual staff is governed by their Contract of Employment, Professional bodies (General Medical Council, HCPC), Staff Code of Conduct, Standing Financial Instructions, Caldicott report and the Data Protection Act. Staff are made aware of this information at induction and on an ongoing basis as part of the Ethics, equality and diversity Competency MF-1029.

All staff must complete Statutory Mandatory LearnPro Training provided by GG and C.

Users' confidential information is also governed by our procedure RL_MP_010 'Management of data and information' and by NHS GG and C I.T. Policy.

The Scottish Microbiology Reference Laboratories, Glasgow are under the professional direction of Professor Alistair Leanord.

He undergoes annual joint review and has a job plan.

Professor Leanord competence is demonstrated in the following ways:

- Participation in Continuing Professional Development (CPD).
- Membership of the Royal College of Pathologists
- Appointment as a consultant by an Advisory Appointments Committee
- Evidence of continuing practice in the specialty
- Recorded attendance at regular departmental meetings to review service issues and to set quality objectives

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The responsibilities of the Head of Department include a range of functions relevant to the services offered by the SMiRL, Glasgow.

Some functions are delegated to members of the Management Group however the Head of Department maintains the ultimate responsibility for the operation of the laboratory.

All non-clinical organisational and administrative duties relevant to the services provided are delegated to Stephen Hughes, the Technical Services Manager.

Duties and responsibilities of Head of Department include but are not limited to:

- Budget planning and financial management – delegated to Assistant General Manager(AGM) and Technical services Manager (TSM)
- Effective liaison with patient population and the healthcare community
- Effective liaison with accrediting bodies and SLE providers – in agreement with (AGM)
- Ensure laboratory is staffed appropriately to provide a service which meets the needs and requirements of users – in conjunction with (TSM)
- Ensure the implementation of the quality policy – delegated to Quality Manger
- Ensure a safe laboratory environment – in conjunction with all staff
- Serve as a contributing member of the medical staff for NHSGG&C
- Ensure appropriate clinical advice is provided with respect to the choice of examinations, use of the service and interpretation of results
- Select and monitor laboratory suppliers – delegated to (TSM) and Site Manager (SM)
- Select referral laboratories and monitor the quality of their service – in conjunction with Quality Manager
- Provide PDP for staff and opportunities to participate in relevant activities out with the laboratory – in conjunction with (TSM)
- Define, implement and monitor standards of performance and quality improvement of the SMiRL, Glasgow service – in conjunction with Quality Manager
- Monitor all work performed in the laboratory to determine that the information generated is clinically relevant.
- Address any complaint, request or suggestion from users or staff – in conjunction with (TSM) and (QM).
- Develop a Contingency plan for emergency situations (resilience) – in conjunction with (TSM) and (SM). There is a plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable. See RL_MP_020 Risk Management (Business continuity) for details.
- Plan and direct research and development.

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4.1.2.1 Management commitment

Management have shown commitment to the development & implementation of the QMS and to continually improving its effectiveness by:-

- Ensuring laboratory personnel are aware of the importance of meeting the needs & requirements of users as well as regulatory requirements by having these as standing agenda items at management meetings, staff meetings and by using CPD accredited quizzes.
- Establishing a quality policy see MAN-QU-1. An original copy signed by the director is displayed at the specimen reception desk. The Quality Policy is reviewed for suitability and effectiveness at the Annual Management review (AMR) meeting.
- Establishing quality objectives & plans. See MAN-QU-3 for the current version. Quality Objectives and Plans are also a standing agenda item at the monthly Senior Scientist meetings. Management ensures the setting of Plans & Objectives by following the Quality Procedure [MAN-QU-4]. These are updated at the AMR
- Responsibilities, authorities & inter-relationships of all personnel are defined under section 4.1.2.5
- Communication processes are described under section 4.1.2.6.
- Appointment of a Quality manager shared on a 50:50 basis with the West of Scotland Specialist Virology Centre.
- There is an annual management review, conducted in January of the following calendar year. MAN-QU-5 defines the conduct of the annual management review.
- Competency assessment is a key component of our training programme. It is assessed & reviewed according to criteria set down in MAN-QU-6.
- Management ensure adequate resources are available by careful selection, induction and training of appropriately qualified staff.
- Accommodation is a state-of-the-art laboratory in the New Lister Building
- Examination processes are verified & validated before use. Processes are continuously monitored by using IQC and EQA checks.
- Pre-examination information for users is contained in the departments website:
<http://www.nhsggc.org.uk/smrl>

4.1.2.2 Needs of users

Medical, Scientific and BMS staff are in daily contact with users to provide support and advice via phone calls and e-mails.

The needs of the users are kept under constant review, and are a standing agenda item at management meetings.

The procedure is defined in ‘Needs & requirements of users’ (RL_QP_003). Needs and requirements of users is a commitment in our Quality Policy (MAN-QU-1).

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They are monitored in a variety of ways including feedback from training days , meetings with specific key users and by individual contact between the Head of department, TSM, Site Manager, Medical Consultants and others who use the service.

Outcomes from these interactions are translated into requirements which are incorporated into quality objectives and plans within in the Quality Management System.

Feedback and complaints are recorded in the CAPA module of Q-pulse and reviewed monthly at the compliance/operational team meetings.

They also form part of the Annual Management Review.

Information for users, including turnaround times, is contained in the user manual accessible via the department's NHS Greater Glasgow & Clyde website:- <http://www.nhsggc.org.uk/smrl>

Turnaround times are agreed between the individual reference laboratories (as providers of the service) and Health Protection Scotland (as purchasers of the service). The turn-around times are monitored by HPS at six-monthly intervals when we submit six-month and annual reports

There is a permanent user feedback link on the website for any comments/suggestions users may have.

There is a permanent user feedback link on this website for any comments/suggestions users may have.

Medical, senior scientific & BMS staff are in daily contact with users to provide support and advice.

4.1.2.3 Quality Policy

The Quality Policy of the Scottish Microbiology Reference Laboratories,Glasgowis published as a separate controlled document (MAN-QU-1) which is displayed at the laboratory entrance. The purpose of the quality policy is to set down, for the information of staff and users, the course of action and measures that the SMiRL, Glasgow has taken in order to provide a service of the highest quality.

4.1.2.4 Quality objectives and planning

The Laboratory Management Group defines the quality objectives of the laboratory and is responsible for ensuring that plans are made to meet these objectives. The management review, which is undertaken on an annual basis, determines whether the objectives have been successfully completed and provides an opportunity for revising objectives and plans and the functioning of the quality management system. See MAN-QU-4 (Establishing Quality Objectives and planning) and MAN-QU-3 (Quality plans & objectives).

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4.1.2.5 Responsibility, authority and interrelations

Head of Department

The Head of Department is a competent individual with responsibility for, and authority over the whole laboratory. The Head of Department is the individual who ensures, on behalf of the laboratory, that all aspects of the laboratory including management organisation and quality, personnel, premises and environment, equipment, information systems, materials and pre-and post-examination processes function correctly.

This is achieved in co-ordination with the Technical Services Manager, Site Manager, Quality Manager, Technical Managers, Clinical Scientists, Biomedical Scientists and Clinical Support Workers.

Technical Services Manager

The Technical Services Manager is the individual who has overall responsibility, for the management of all aspects of the laboratory including, quality, personnel, premises and environment, equipment, information systems and materials and that examinations both pre and post function correctly. This is achieved in coordination with the Head of Department, Site Manager, Quality Manager, Technical Managers, Clinical Scientists, Biomedical Scientists and Clinical Support Workers.

Site Manager

The Site Manager is the individual who ensures, on behalf of the laboratory, that the management of all aspects of the laboratory including, quality, personnel, premises and environment, equipment, information systems and materials and examinations both pre and post function correctly. This is achieved in coordination with the Head of Department, Technical Services Manager, Quality Manager, Technical Managers, Clinical Scientists, Biomedical Scientists and Clinical Support Workers.

Quality Manager

The quality manager is the individual who ensures, on behalf of the laboratory management, that the quality management systems function correctly. This is achieved in co-ordination with the Head of Department, Technical Services Manager, Site Manager, Technical Managers, Clinical Scientists, Biomedical Scientists and Clinical Support Workers.

The Quality Manager reports to the Technical Service Manager and also to the Assistant General Manager

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The following personnel have designated roles within the SMiRL, Glasgow:-

Staff member	Post	Deputy
Professor Alistair Leanord	Head of Department – Director Reference Laboratories	Dr. Brian Jones
Stephen Hughes	Technical Services Manager	Pamela Saunders
Pamela Saunders	Site Manager	Alistair Brown
Jane McOwan	Quality Manager.	Cheryl Johnston
Alistair Brown	Training Officer	Fiona Shaw
Michael Coyne	IT Manager	Edwin Yip and Sarah Rankin.
Pamela Saunders	Health & Safety Officer	Maria Riley

See Appendix 1 for interrelationships

4.1.2.6 Communication

The communication & committee structure of internal & external communications is shown below. The committee structures within Levels 4 and 5 of the New Lister Building have been reviewed with the intention of simplifying & streamlining activity in areas common to all departments i.e. West of Scotland Specialist Virology Centre, Scottish Microbiology Reference Laboratories, Glasgow (both Level 5) and Microbiology North Sector (Level 4)

National Services Division and Health Protection Scotland - Meets annually. The service planning meeting is attended by the SMiRL, Glasgow Director, the Technical Services Manager, Site Manager and relevant Clinical Scientists

Microbiology Management Team – Greater Glasgow & Clyde

Every 4-6 weeks.

Attended by:

Clinical Director,
General Manager,
Assistant General Manager,
Head of Microbiology Services,
Lead Microbiologists,
Head of Department SMiRL, Glasgow,
Consultant staff SMiRL, Glasgow,
Technical Services Managers
Quality Managers

Meetings are held in “partnership” with staff side representatives.
This is a GG&C wide meeting to discuss all aspects of the clinical service

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SMiRL, Glasgow / WoSSVCCCompliance / Operational Team Meeting

Every 4-6 weeks

Attended by:

Technical Services Manager
 Site Managers
 Quality Manager
 Training Officers
 IT managers
 Health and Safety Officer (TSM)
 Chaired by the Technical Services Manager

Compliance reports are reviewed and any issues discussed and placed on action tracker - reports include:

- Review of Quality Objectives and Plans Needs and Requirements of Users
- Risk Register
- Non-conformances/Datix/Complaints
- Health and Safety including CL3, IQC and EQA results
- IT Data Quality

This report covers any issues arising from the quality management system and also all areas of the laboratories pre-examination, examination and post examination processes.

Operational issues relating to SMiRL, Glasgow and WoSSVC are also discussed and actioned.

Senior Scientist's meeting

Every 4-6 weeks

Attended by:

Consultant staff
 Technical Services Manager
 Site Manager
 Quality Manager
 Technical Managers
 Office manager

Chaired by the Technical Services Manager, and is attended by the Site Manager, team leaders (BMS, Clinical Scientist and clerical staff) and the Quality Manager. All operational issues are discussed.

The Quality Manager presents a compliance report which includes trending of non-conformances and turnaround times for tests. The audits for the coming month will be discussed and scheduled with the appropriate team leaders.

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Team leaders present a section report – this includes trending of IQC/QC results, EQA results and audit findings discussed. Every six months measurement of uncertainty report is written and discussed at this meeting.

Any issues arising from these reports are actioned.

This meeting deals with any issues arising from the quality management system and also all areas of the laboratories pre-examination, examination and post examination processes.

Where appropriate, information from the Management Group will be discussed by the Technical Services Manager, and any issues raised here can be discussed at the relevant meeting, *e.g.* Clinical Group.

Information from this meeting is cascaded to individual team members at regular informal meetings within each section.

All Staff Meeting – Thursday morning update meeting

Weekly.

Full staff meetings are held weekly. These meetings are chaired by the Technical Services Manager or Site Manager, and act as a channel for informing staff of proposed changes, or other relevant information that may affect management structure or laboratory procedures. It is also an opportunity for staff side and all staff to raise issues or complaints relevant to the efficient running of the laboratory. On the first Thursday of each month the TSM holds a joint meeting with all SMiRL, Glasgow and WoSSVC staff.

Any staff suggestions raised through documents placed in the staff suggestion box are recorded in Q-Pulse and discussed at this meeting. Outcomes are also recorded in Q-Pulse

New Lister Building Health and Safety Committee

Four times a year.

The Laboratory representatives are:-

Technical Services Manager
 Site Managers
 Quality Manager
 Health & Safety Co-ordinator

The Health and Safety Committee is a unified group representing Level 4 and level 5 of the New Lister Building. It meets quarterly, a representative from each grade of staff of the laboratory attends. Staff may ask a committee member to raise a concern at the next meeting. All safety issues are considered, including accidents (and near misses) and audits of the

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premises. Issues raised are passed to the relevant Technical Services Manager for action, or discussed at the Microbiological Operational Management Group, as appropriate.

All above meetings are minuted.

Additional communication methods

Information within the laboratory is also cascaded to staff through the use of e-mailed memos. The contents of these memos are discussed at the Thursday catch up meetings with all staff.

There is also a meeting that allows Health care support workers and biomedical staff to meet separately to discuss any issues/concerns they may have. These notes are fed back to the TSM and Quality Manager.

NHS Greater Glasgow and Clyde send out regular ‘Core Briefs’ and Monthly News Letters to all staff by e-mail – this keeps staff up to date with developments.

To view Staff Communications online, visit: www.nhsggc.org.uk/staffcommunications

Follow NHSGGC on Twitter: [@nhsggc](https://twitter.com/nhsggc)

There are also NHS GG&C, General Notification e-mails sent as and when necessary by the board which alert the relevant staff to various issues for example ‘downtime’ in the Datix reporting system for maintenance

4.1.2.7 Quality Manager

The Quality Managers post is shared on a 50:50 basis with the West of Scotland Specialist Virology Centre. The Quality Manager reports directly to the Technical Services Manager and also the Assistant General Manager of Diagnostics.

The Quality Manager has delegated responsibility for establishing, implementing and maintaining a quality management system and reporting to management on its performance and needs for improvement.

They provide support and advice to senior staff on quality management matters at service and directorate level and monitor the requirements of the Department’s users and ensure that they are reflected within defined quality performance measures.

4.2 Quality management system.

4.2.1 General requirements and Overview of system

Laboratory management demonstrates its commitment to fulfilling the needs and requirements of its users by clearly defining the way in which the laboratory is organised and managed.

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The laboratory has established and implemented a robust quality management system as documented in this Quality Manual and associated procedures.

Evidence that we have established a quality management system includes:-

- Our Quality Manual, Quality Policy, the appointment of a quality manager and the implementation of a quality management system.
- The QMS processes and application, criteria and methods, availability of resources and its monitoring for improvement action are set down in documents held in Q-Pulse.

The key ones are:-

- MAN-QU-2 ‘Quality Manual.’
- MAN-QU-1 ‘Quality Policy’.
- MAN-QU-3 ‘Quality Objectives and Plans.’
- RL_QP_008 ‘Document control and review.’
- MAN-QU-5 ‘Annual Management review.’

The effectiveness of the SMiRL, Glasgow Quality Management System and the processes within it are monitored through planned and scheduled internal audit processes, against agreed criteria, by personnel trained in internal audit. See RL_QP_023

4.2.2 Document requirements

4.2.2.1 General

The laboratories Management Team defines the quality objectives of the laboratory and is responsible for ensuring plans are made to meet these objectives. The management review which is undertaken on an annual basis, determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and the functioning of the quality management system.

All policies and procedures are available via Q-Pulse.

4.2.2.2 Quality Manual

This Quality Manual (MAN-QU-2) is underpinned by the department laboratory and management procedures. It is the responsibility of the Quality Manager to ensure the implementation and monitoring of the quality management system, and it is the responsibility of Laboratory Management to ensure that the correct resources are in place to allow implementation and continuation of the quality management system.

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4.3 Document control.

Document control is an essential component of the Quality Management System.

All documents (internally generated and from external sources) required for the Quality Management System will be subject to the Laboratory's document control procedures.

The laboratory utilises the Q-Pulse Quality Management Software to assist in an effective document control system. All documents within the quality management system for use in the SMiRL, Glasgow must be stored/managed on Q-Pulse allowing full traceability.

All documentation is properly controlled. SOPs, forms, work instructions and external documents have a unique identifying code, review date, version number, pagination and name of authoriser (owner), which correctly identifies the type, number and version of the document.

Documents cannot be amended on Q-Pulse without the required privilege level and all the controlled documents are printed with coloured headers and footers. Only active documents are at workstations with obsolete or inactive documents removed and stored indefinitely electronically only. Refer to RL_QP_008 Document control and review

4.4 Service agreements

4.4.1 Establishment of service agreements

4.4.2 Review of service agreements

We aim to establish service agreements by discussion with our parent organisation Health Protection Scotland. This benefits the department because it allows planning of resources for the period of the SLA. It benefits users because they are made aware of what services we offer. The mechanism for establishing a SLA is explained in the next section.

Establishment & review of service agreements

Service Level Agreements – National Reference Laboratories

A National Reference Service is established on the basis of the identification of a specific Clinical or Public Health need, either by the Reference Laboratory Working Group (RLWG) or Health Protection Scotland (HPS). If approved by the Scottish Government HPS will authorise a “Service Level Agreement” (SLA) with the specific Health Board to provide the service. This is along the lines of a purchaser / provider agreement where HPS, part of National Services Scotland (NSS), acts as the purchaser. NHS Greater Glasgow & Clyde acts as the provider.

The service level agreement normally runs for three year periods and will include:

- the range of services provided,
- financial agreements,
- acceptable levels of service delivery,
- roles and responsibilities of each of the parties.

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The contract contains Key Performance Indicators which will be used by HPS to measure the performance of the service. These will include: - activity, quality objectives and turn-around times for each part of the service provided. NHS Greater Glasgow & Clyde will submit six-month and annual reports as outlined in the SLA and these will be discussed at formal meetings with HPS / NSS at joint twice-yearly meetings.

4.5 Examination by referral laboratories.

4.5.1 Selecting & evaluating referral laboratories & consultants

As we are a reference facility very few samples have to be sent away however we still carefully select which referral centres we use, for the benefit of our users. The SMiRL, Glasgow makes every effort to use other Laboratory services that meet **ISO 15189:2012** standards. This will ensure that the quality of our service is not compromised by the actions of a third party. See RL_QP_014

4.5.2 Provision of examination results.

We aim to provide accurate results for our users by ensuring that our procedures state that we, as the referring laboratory, are responsible for ensuring the results from the referral laboratory are delivered to the person making the request. See RL_MP_003 Reporting results.

4.6 External services & supplies

We aim to continually improve the quality of our service by carefully selecting suppliers, and by regularly reviewing their performance.

Consideration is taken of:

- Quality of service
- Professionalism
- Costs
- Contractual obligation
- Recent performance
- Availability of stock
- Time to delivery
- Partnership

See RL_MP_008 Management of materials & reagents and RL_QP_019 Evaluation, selection and review of suppliers for further details.

A list of selected and approved suppliers is stored in Q-Pulse

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4.7 Advisory services.

We aim to maintain close contact with our users in order to ensure that the service meets their needs and requirements.

Communication with users is kept under constant review. In practice, this is achieved by user-satisfaction questionnaires, meetings with specific key users and by individual contact between the Head of department, TSM, Site Manager, Medical Consultants and others who use the service. See MAN-QU-7 'Needs and requirements of users'.

The Laboratory User Guides are published as part of our website. <http://www.nhsggc.org.uk/smrl> this gives guidance on how to use the service and available examinations including sample types and any additional requirements or limitations. Contact details for medical staff and the laboratory management team for additional technical or logistical advice are listed on the website.

4.8 Resolution of complaints.

We aim to continually improve the quality of our service by building confidence in our users that complaints will be thoroughly investigated and corrective action taken. All complaints will be logged within the CAPA module in Q-Pulse.

The process is:-

- To take all complaints seriously.
- To deal with the client in a courteous manner.
- To try to resolve the issue immediately at a local level.
- To inform the client about the progress of the complaint.
- To make corrective action as soon as possible.
- To investigate root cause analysis to prevent recurrence

See RL_QP_006 Complaints procedure

There is also a documented procedure for laboratory staff to follow when raising a complaint.
See RL_MP_004 Information for staff

4.9 Identification and control of non-conformities

There are many possible sources where non-conformance may be identified within the laboratory including:

- Internal audit
- External audit
- QC failure
- Instrument failure
- Calibration failure
- Complaint
- Product/reagent recall or failure

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These are all managed in the same way e.g. identify the non-conformance, report the non-conformance using Q-Pulse, investigate to find the root cause, put into place corrective action to prevent the incident occurring again and review to check that any corrective action has been successful.

We aim to ensure that nonconformities are effectively managed in order to build confidence in our users and to continually improve our service.

Non-conformity reports from all areas of the Quality management system including the pre-examination, examination and post-examination processes are documented and appropriately managed so as to minimise risks to service users.

These are submitted to the quality manager as they arise, and cumulative data forms part of the monthly compliance report and annual management review.

The identification and control of non-conformances is described in MAN-QU-9 Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).

4.10 Corrective action.

A corrective action deals with a nonconformity that has occurred. Actions taken can be both immediate (remedial) and long term to prevent the incident occurring again.

Removing the root cause of a problem is the true corrective action as it prevents the issue happening again

We investigate and, where possible, remove the root cause of all nonconformities.

See MAN-QU-9 Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).

All non-conformances raised are investigated and corrective action implemented by the designated person in discussion with the Quality manager/Site manager. This corrective action is recorded in the CAPA record in Q-Pulse along with any evidence of implementation available.

The Quality manager reviews all non conformances and presents a report at monthly meetings including the number of NCs recorded, number in progress, number closed and number overdue. From this the % performance is calculated and reported.

If the NC has been raised from an audit – a re-audit is scheduled to establish if the corrective action has been effective.

4.11 Preventive action

A preventive action is a change implemented to address a weakness in the system that has the potential to allow non-conformity to occur.

It is a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints.

Audits can highlight areas that require preventative action e.g. a potential for transcription error is witnessed and an extra check is included into the procedure. There are however many other areas apart from review of operational procedures that could instigate preventative action including trend analysis of QC data and EQA results.

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Preventative action is to avoid creating non-conformities but it also often includes improvements in efficiency.

Within the lab preventative action includes:

- Equipment service and calibration – this ensures the equipment e.g. pipettes perform as expected reducing potential non-conformities
- Validation/verification - gives evidence that the process is operating within established parameters effectively, giving consistent results meeting predetermined specifications established to fulfil the requirements of the laboratory
- Reporting of QC performance to the senior scientist monthly meeting
- Analysis of any EQA IQA failure for root cause
- Pre-acceptance of kits before use
- Change control of e.g. any changes in IT
- Recording daily temperatures of fridges / incubators (for drift trending)

Preventative action is agreed between the Technical manager, Site Manager and Quality Manager. Any preventative action implemented is recorded in the CAPA module of Q-Pulse. Were appropriate a re-audit or review of data must be carried out to establish if the preventative action has been effective.

See MAN-QU-9 Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).

4.12 Continual improvement

We aim to ensure that the service meets the changing needs and requirements of our users by having evaluation and improvement processes in place including:

- Assessment of user satisfaction MAN-QU-7.
- Regular discussion with users of the service to discuss service needs.
- Participation in clinical meetings.
- Internal audit of examination processes RL_QP_023
- Internal audit of the quality management system RL_QP_011
- External quality assessment RL_QP_021
- A process for continuous quality improvement (RL_QP_012).
- Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).MAN-QU-9
- Quality indicators MAN-QU_8

The results of these evaluation and improvement processes are available to staff and users as required. Analysis, recording and interpretation of the data, forms part of the management reviews which are contained in the annual review.

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Quality objectives and plans - MAN_QU_3 are set at the beginning of each year after completion of the Annual Management Review. They are regularly reviewed by the laboratory management team and the document updated quarterly. This document is communicated to staff via Q-Pulse document acknowledgement sign off.

Error logs, assessment reports and complaints are presented by the Quality Manager to monthly senior scientific staff meetings as well as to the Annual Management Review. Outstanding non-conformances are investigated by the Quality Manager with timescales set for corrective action.

Performance in EQA schemes are analysed by the Technical Manager of the appropriate section and then summarised at the meetings. Corrective action is taken as appropriate. The Quality Manager will monitor that both remedial and corrective actions have been taken and recorded.

User surveys, complaints and training are discussed at the Senior Scientists' meetings and information is disseminated to the staff during full staff meetings. Staff suggestions are encouraged by using an initiative and suggestion form RL_QF_002 which can be returned anonymously if preferred by using the Suggestion Box - these are recorded in Q-Pulse.

Suggestions can also be raised directly in Q-Pulse by any staff member. Staff feedback/concerns are voiced at the full staff meetings.

4.13 Control of records.

We aim to adhere to the rules governing record control, in order to ensure accuracy and availability of all aspects of our service. The process is defined in RL_QP_008 Document control and review. Records and specimens are stored in accordance with RCPATH & IBMS guidelines (see ED-1 in Q-Pulse). Quality records are available in Q-Pulse or from the quality manager. Process records are stored at workstations or are archived. Disposal of these records is in accordance with the NHSGG and C policy on confidential waste.

4.14 Evaluation & audits.

4.14.1 General

We aim to continuously interrogate our service by a system of audits, in order to detect weaknesses before they cause an error. There is planned and scheduled internal audit of the pre-examination, examination and post-examination processes against agreed criteria, by personnel trained in internal audit. See RL_QP_023 These audits ensure conformity to the Quality Management System and contribute to improving its effectiveness.

All processes are validated or verified before introduction into the laboratory to ensure their performance meets the needs and requirements of our users.

Results of these are discussed at the annual management review

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4.12.2 Periodic review of requests, and suitability of procedures and sample requirements

The laboratory test repertoire is monitored by medical staff who review requests made for referral tests. Amendments to the lab repertoire is discussed in management meetings and reviewed during the annual management review. There is guidance in the User Guide published on the website regarding sample requirements with regard to collection, storage and transport which are periodically reviewed.

4.14.3 Assessment of user feedback

User satisfaction is assessed formally using a ‘user questionnaire’ which is distributed by HPS before renewal of SLAs. The data gathered is analysed, and areas for improvement identified. There is also a permanent user feedback function on our website.

Informal meetings with users are undertaken by SMiRL, Glasgow staff in person during visits, or by telephone and e-mail interactions. Any issues arising from telephone calls or e-mails will be passed to the quality manager to deal with
User complaints are dealt with according to the Clinical Adverse Patient Incident Reporting Policy, and the SMiRL, Glasgow Complaints procedure.

User feedback and review is a standing agenda item at the Monthly Senior Management Meeting. Any feedback will be recorded by the Quality Manager in Q-Pulse as a ‘FBN’ feedback notice

4.14.4 Staff suggestions

The identification of improvements is a pro-active process and forms part of the continual improvement process in the laboratory. Staff are encouraged to identify possible improvements to the quality system or to test procedures. Suggestions can be made at any time but are most likely to be made during internal quality audits.

Suggestions can also be raised anonymously using RL_QF_002 Initiative and suggestion form and placing it in the suggestion box – these will be recorded in Q-Pulse. Staff suggestions can also be raised and recorded using the CAPA module on Q-Pulse by any member of staff. Staff suggestions and feedback is a standing agenda item at the 5th Floor all staff meeting to encourage staff to participate and to feedback on any suggestions made.

4.14.5 Internal audit

We aim to continuously interrogate our service by a system of audits, in order to detect weaknesses before they cause an error. There is internal audit of the pre-examination, examination and post-examination processes, which is planned and scheduled - see RL_QP_023 against agreed criteria, by personnel trained in internal audit.

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The records of internal audit include:

- The activities, areas or items audited.
- Any nonconformities or deficiencies found.
- Recommendations and time scale for corrective and preventive actions.
- The results of internal audit are regularly evaluated and decisions taken are documented, monitored, reviewed and acted upon.
- Audit findings are communicated to appropriate personnel. In addition audit records are available for scrutiny within Q-Pulse.

Internal audit of the QMS is defined by RL_QP-011 - The audit schedules are held in QPulse.

4.14.6 Risk Management

We aim to establish business continuity in order to fulfil our responsibilities under the overall objective of providing a safe environment for patients, staff and visitors as well as to comply with relevant legislative requirements. This requires contingency planning by management and is detailed in RL_MP_020 Risk Management - Business continuity.

4.14.7 Quality indicators

Quality indicators are established by the management team prior to implementation. The objectives, methodology and duration of measurement are detailed in MAN-QU-8

4.14.8 Review by external organisations

External reviewers can include UKAS and Health and Safety Executive. Any non-conformities raised externally are followed up immediately or by required timeframe and reported back to the relevant organisation. Reports are stored in Q-Pulse, any information gathered as part of external assessment contributes to continual quality improvement within the laboratory.

4.15 Management review

We aim to regularly review our quality management system, in order to ensure its continued suitability, adequacy & effectiveness in support of patient care.

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4.15.2 Review input

The Laboratory management team conduct an annual review which considers the following items of information (see MAN-QU-5):

- the periodic review of requests & suitability of procedures & sample requirements
- assessment of user feedback
- staff suggestions
- internal audits – including any improvement findings
- risk management
- use of quality indicators
- reviews by external organisations
- results of participation in inter-laboratory comparison programmes
- monitoring & resolution of complaints
- performance of suppliers
- identification & control of non-conformities
- Results of continual improvement including current status of CA/PA
- follow up actions from previous management reviews
- changes in the volume & scope of work, personnel & premises that could affect the quality management system
- recommendations for improvement, including technical requirements.

These are all reviewed to identify any issues/trends developing which could highlight developing problems with process

4.15.4 Review output

A record of the meeting is compiled by the Quality manager – Q-PulseMF006. This report is communicated to all staff. Q-Pulse acknowledgement is implemented.

The meeting is a review of Quality Management System, policy and objectives.

The objectives set at the beginning of the year during the AMR of the previous year are reviewed again for progress/completion.

Discussions take place between management including possible improvements to the service the laboratory delivers to users, any improvements that could be made in the Quality management system and its processes and also how to facilitate these improvements.

These outputs form quality objectives for the forthcoming year and are documented in MAN-QU-3 in Q-Pulse and communicated to staff

The AMR includes root cause, trending of non conforming work e.g. IQC, EQA results etc to identify any patterns that may indicate there is a problem with a process and improvement opportunities.

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5.0 Technical requirements

5.1 Personnel.

5.1.1 General

See RL_MP_004 Information for staff

5.1.2 Personnel qualifications

A record of each staff member's qualifications, training and copies of HCPC Registration certificates (if appropriate) are kept in the site managers' office.

5.1.3 Job descriptions

To allow each member of staff to know their duties, responsibilities and rights they are given written job descriptions.

Job descriptions include:

- Job title
- The location within the organisation
- Accountability
- Main purpose of the job
- Main duties and responsibilities
- Staff annual joint review

All staff have a contract of employment, which is in compliance with current legislation and provides clear terms and conditions of service.

Job descriptions are available as controlled documents via the Q-Pulse document control software.

5.1.4 Personnel introduction to the organisational environment

GG&C Health Board has a comprehensive staff orientation and induction programme. An induction pack is issued on or before a new employee's starting date and local induction training is carried out on the first day of work.

This local induction training covers such areas as:

- Department/Division information
- Working environment
- Terms and conditions of employment
- Patient confidentiality and data protection
- Health & Safety
- Job description including an organisational chart
- Salaries and wages
- Staff facilities
- Equality and Diversity
- Records of staff orientation and induction are kept in individuals personal files.

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5.1.5 Training

Trainee BMS staff participate in courses at Glasgow Caledonian University according to the requirements set by the IBMS for eligibility for HCPC registration. Trainee BMS staff are required to complete the IBMS Competency Portfolio to enable them to become registered.

Registrant BMS staff are then required to complete the IBMS Specialist Portfolio. They are also actively encouraged to participate in MSc courses. All trainee scientists and medical staff will follow the appropriate training manual and maintain the log book. All trainees will be reviewed on a regular basis on completion of each training section and in the annual review.

Professional development of all staff is encouraged. A professional development system is available via the Institute of Biomedical Science, and BMS staff are encouraged to participate in this scheme. It is mandatory for all HCPC registered staff to demonstrate continued professional development. The Royal College of Pathologists has a CPD scheme for all College members in career grade posts (consultant and non-consultant); non-medical and Clinical Scientists are eligible to register.

Rotation through the laboratory for less qualified staff is an essential element of training for HCPC registration purposes. Qualified staff may also be expected to rotate as required for the efficient running of the laboratory.

All staff must complete the NHS GG+C Statutory / Mandatory on line courses using LearnPro modules :

GGC: 001 Fire Safety, GGC: 002 Health and Safety, An Introduction. GGC: 003 Reducing Risks of Violence & Aggression, GGC: 004 Equality, Diversity and Human Rights, GGC: 005 Manual Handling Theory, GGC: 006 Public Protection (Adult & Child), GGC: 007 Standard Infection Control Precautions, GGC: 008 Security & Threat and NES: Safe Information Handling – Foundation.

5.1.6 Competence assessments

There are competence records held for all processes in the department and individual records are kept for all staff members.

5.1.7 Review of Staff performance

Staff annual joint review is carried out in accordance with health board policy.

All staff participate in an annual joint review (Turas PDP) which includes consideration of:

- Outline for the job role.
- The quality objectives and plans of the laboratory.
- The current job content.
- Documentation of training needs and agreed personal objectives with the appraiser.

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- Evidence that management has recognised the agreed development needs of individual staff members.

All staff performing Turas PDPs have been trained and records of all staff PDPs are kept.

5.1.8 Continuing education and professional development (CPD)

It should be noted that all of the SMiRL, Glasgow groups/committees have a training element and should be attended by trainees where possible.

All staff are encouraged to participate in "Continuing Professional Development" (CPD), which is now mandatory for continuing registration with HCPC.

Opportunities for further education and training are available in relation to the requirements of the service and individual personal development.

The Department provides resources for such education that includes:

- Access to library and information services.
- Suitable accommodation for private study.
- Opportunity to attend meetings, seminars and conferences.
- Financial support.

Records of training and education are kept for each member of staff.

5.1.9 Personnel records

The Human Resources Department of the Diagnostic Directorate of the Acute Division of NHS Greater Glasgow and Clyde holds the complete staff record. The Occupational Health Department holds vaccination records and the Pay Department holds records of payments. In addition, confidential staff records are kept including:

- Personal details.
- Employment details.
- Job description.
- Terms and conditions of employment.
- A record of staff induction and orientation.
- A record of attendance at fire lectures.
- A record of attendance at manual handling courses.
- A record of education and training.
- Relevant educational and professional qualifications.
- Certificate of registration with the Health & Care Professions Council (HCPC) were appropriate.
- Absence record.
- Accident record.
- Record of annual joint review.
- Occupational health record.

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- A record of disciplinary action (for relevant period)

All of the above paperwork is held with the site manager

5. Accommodation & environmental conditions.

A laboratory requires sufficient space to ensure that work is performed safely & efficiently. We aim to ensure that the SMiRL, Glasgow provides a working environment in which staff can perform required functions in accordance with national legislation and guidelines. The premises are a state-of-the-art building which meets all current regulations for medical laboratory accommodation.

The premises have space for:

- Specimen reception
- The functioning and use of all equipment.
- Separation of incompatible activities (e.g. Office and laboratory).
- Storage facilities.

Access to the premises is by swipe card entry *via* locked doors.

5.2.1 General

We aim to ensure there is a working environment in which staff can perform required functions in accordance with national legislation and guidelines. The premises are a state-of-the-art building which meets all current regulations for medical laboratory accommodation.

The premises have space for:

- Specimen reception.
- The functioning and use of all equipment.
- Separation of incompatible activities (e.g. Office and laboratory).
- Storage facilities.
-

Access to the premises is by swipe card entry via locked doors.

5.2.2 Laboratory and office facilities

These are well separated / demarcated.

5.2.3 Storage facilities

Paper-light systems operate with regards to reports and storage of paper records. Scanning options are available. Consumables and reagent storage is appropriate with large functional areas (cold and ambient).

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5.2.4 Staff facilities

Common room refectory, with cooking, eating and drinking facility provided. Toilets, including disabled, shower facilities are plentiful and substantial.

5.2.5 Patient sample collection facilities

(N/A)

5.2.6 Facility maintenance and environmental conditions

Refurbished building with new temperature and air management systems in place. Quarterly workplace inspections are carried out and reported to facilities.

Laboratory management's safety responsibilities are defined in the Health & Safety Manual and in the Division's H&S Policy. A hard copy of this manual is kept in the Site Managers office.

5.3 Laboratory equipment, reagents & consumables.

We aim to ensure that sufficient & appropriate equipment is available so that service quality is at the highest level. A commitment to this effect is included in the quality manual and in document RL_MP_007. This includes rules for equipment procurement.

See the equipment inventory & laboratory equipment records for further details.

5.3.1 Management of equipment

There is a procedure for procurement and management of equipment (RL_QP_007).

The procedure contains:-

- Assessment and Justification of Need
- Selection
- Evaluation of Suppliers
- Purchasing arrangements
- Establishment and Maintenance of an Equipment Inventory File
- Equipment Maintenance, Service and Repair

An Inventory of equipment is maintained in Q-Pulse, which includes:

- Manufacturer's name.
- Serial number.
- Date of purchase or acquisition.
- Maintenance contract.

The Estates department performs electrical safety testing (PAT) on a regular basis.

A decontamination certificate is issued before an engineer is allowed to work on the appropriate item of equipment (SMRL_WF_001).

Requirement for new equipment is highlighted to the Management Group *via* the Laboratory Manager's Group. A business case is put forward to the Directorate for all new equipment, including upgrading of existing equipment. Selection of appropriate equipment is based on

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laboratory requirements and cost. Quotations/tenders are obtained from suppliers/manufacturers. A safety assessment is carried out for the positioning of the equipment in the laboratory, and any special requirements noted.

For all items over £5000, completion of a Capital Equipment Request Form is required. For all items under £5000, (including IT equipment), the appropriate forms are submitted to the Directorate for approval. A centrally held budget is available for equipment within this category.

Training is directed by the supplier/manufacturer of the equipment, and where appropriate both off-site and on-site training are given.

Maintenance agreements and scheduled service visits are arranged with the Technical Services Manager. Service and breakdown reports and corrective action taken are filed in Q-Pulse.

User, maintenance and decontamination procedures are described in equipment SOPs (EOPs). Disposal of redundant/ broken equipment is arranged through the relevant company or GRI Estates department, and the equipment removed from the asset register.

5.3.1.2 Equipment acceptance testing

All new and replacement equipment is assessed before being put into use. This includes:

- Health & safety implications
- Throughput
- Trial by comparison with current methods by testing both methods in tandem.
- Management review of costs, supply, equipment, staffing and service issues.
- Production of business plan and specification

5.3.1.3 Equipment instructions for use

Sufficient and appropriate equipment is provided to meet the needs and requirements of the users. This is regularly maintained and all staff are instructed in its correct use. Training and competency records for all examinations processes, including the use of the relevant equipment are maintained. Instructions for use are in individual SOPs where applicable and manufacturer's manuals are available either electronically or as hard copies.

5.3.1.4 Equipment calibration and metrological traceability

Appropriate calibration of equipment is detailed in relevant SOP/EOPs. Calibration may also be performed by the manufacturer as part of periodic service and preventive maintenance. Records of calibration, where provided, are stored on Q-Pulse.

The following UKAS documents provide further information on metrological traceability and the calibration of lab equipment to ensure conformity with **ISO 15189:2012**:

- TPS 41: UKAS Policy on Metrological Traceability ED-197.
- LAB 14: In-house Calibration and Use of Weighing Machines ED-194
- LAB 15: Traceability: Volumetric Apparatus ED-199

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For further information see LAB 5 Reporting Calibration Results ED-198 and LAB 11: Traceability of Temperature Measurement ED-84.

5.3.1.5 Equipment maintenance and repair

Day to day maintenance of all equipment is carried out and recorded according to manufacturers' instructions.

The Manufacturers or service contractors perform service checks and repair of all equipment. The laboratory management holds all purchase and service contracts. Engineer's reports are held electronically within the Asset record.

All equipment undergoes PAT Electrical safety checks, carried out by the Estates Department and is marked accordingly.

5.3.1.6 Equipment adverse incident reporting

Adverse incidents and accidents involving equipment are reported through the GG&C IntraNet DATIX system where appropriate actions and follow up are recorded.

Equipment faults are logged within the Q-Pulse asset record where details of notification to manufacturers, repairs and engineers' visits are recorded. Other general issues with equipment suppliers are recorded as Supplier non-conformances in Q-Pulse.

5.3.1.7 Equipment records

An inventory of all laboratory equipment is held in Q-Pulse. This is reviewed annually and includes Serial Number, Asset Number and date of purchase.

5.3.2 Reagents and consumables

5.3.2.1 General

Reagents, consumables, calibrators and quality control materials are purchased from appropriate suppliers and manufacturers in adequate quantities to ensure continued provision of service.

A procedure (RL_MP_008) is established for the management of reagents and materials:

- Selection, purchasing and ordering.
- Assessment of suppliers.
- Receipt and verification of identity and condition.
- Issue and inventory management.
- Safe disposal.

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The SOP for reviewing suppliers is RL_QP_019.

Materials in use are correctly identified with date of receipt, lot numbers and expiry.

All purchasing of reagents and consumables material is in line with the Health Boards Standing Financial Instructions ED-203.

Purchasing of all materials is through approved suppliers. Materials are selected following evaluation of their suitability by the laboratory. Orders are placed electronically onto the supplies PECOS system and, dependant on the value, are authorised by appropriate staff. Orders up to £5000 can be authorised by the Technical Services Manager and deputy up to £2,500 and orders are e-mailed to suppliers via the PECOS system.

All other materials, either “stock” (*i.e.* NHS supplied), or non-stock items are ordered electronically through the PECOS system by generating a unique order number, identified as a SMiRL, Glasgow order.

Specimen reception staff receives goods from delivery driver.

Open goods, take out delivery note date stamp and initial establish what section has ordered the goods, photocopy delivery note and pass to an appropriate member of staff along

Match up delivery note with P.O. and place in tray at reception for Level 1 admin staff to GRN.

For reagents it will be the responsibility of staff from the relevant section to record pre acceptance details and put the goods away to appropriate fridge / freezer / Coldroom.

For consumables / plastics etc these should be placed into stock in the appropriate store.

The SOPs also contain COSHH references and describe the appropriate handling precautions and safe disposal of all materials. Materials in use are correctly identified with the date of receipt, lot numbers, first use and expiry date.

5.3.2.2 Reagents and consumables — Reception and storage

Reagents and consumables are delivered directly to the department and are signed for by laboratory staff. This is recorded in LS-F-036 - Receipt of goods delivered.

Reagents are checked on arrival for damage or missing reagents and stored according to manufacturer's instructions.

5.3.2.3 Reagents and consumables — Acceptance testing

Acceptance testing of kits and reagents is performed prior to use in examinations to verify performance. This is carried out and recorded according to individual Work Instructions

5.3.2.4 Reagents and consumables — Inventory management

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Stock control is through stock logs in each section of the laboratories where specific records are kept. All reagents are handled as detailed in individual standing operating procedures

5.3.2.5 Reagents and consumables — Instructions for use

Instructions for use of kits and reagents are outlined in bench SOPs specific to the test in question. See laboratory procedures on Q-Pulse.

5.3.2.6 Reagents and consumables — Adverse incident reporting

See also section **5.3.1.6**.

Adverse incidents and accidents involving reagents are reported through the GG&C IntraNet DATIX system where appropriate actions and follow up are recorded.

Technical issues with reagents or suppliers are logged non-conformances in Q-Pulse.

5.3.2.7 Reagents and consumables — Records

Records are kept of all reagents used in the performance of examinations including date of receipt, lot numbers, expiry date and results of acceptance testing. See individual process SOP/EOPs

5.4 Pre-examination processes.

We aim to ensure that our users are fully aware of our service in order that they can make the best use of it. The information including how to contact us, how to correctly send specimens for analysis, and how to obtain clinical advice is available in the user manuals displayed on the web site see www.nhsggc.org.uk/smrl. This also includes which of the tests we offer are on our UKAS accredited scope.

Information for users and patients

The information for users includes:

- Contact details of key staff
- Location of the laboratory
- Opening hours
- Instructions for specimen transport
- Availability of clinical advice and interpretation
- The repertoire of tests offered, specimen type required and turnaround time
- Key factors which are known to affect the validity of results

Request form

The request forms are designed to include:

- Sufficient information to allow unique identification of the patient
- The source of the request

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- The requesting individual
- The date and time of specimen collection
- Specimen type and where appropriate the anatomical site of origin
- The investigation required
- Relevant clinical information
- Location to which report should be sent (including copy report)
- The unique laboratory accession number

The date & time of receipt at the laboratory is recorded using either a date/time electronic stamp or in the LIMS if PID done upon and at computer entry (PID).

The department encourages proper completion of the request form.

Specimen collection and handling

- Checking the completion of the request form and confirming the identity of the patient
- Checking that the specimen container is correctly labelled
- Ensuring that the specimen is correctly collected
- Minimising the risk of interchange of samples and sub samples
- Ensuring that environmental and storage conditions are fulfilled
- Ensuring the safe disposal of all materials used in specimen collection
- Ensuring that high risk specimens are identified and processed correctly
- Ensuring that all spillages and breakages are dealt with correctly
- Minimising the risk to ensure the safety of the specimen collector carrier, the general public and the receiving laboratory

Specimen transportation

- The GG&C Specimen Transport Policy fulfils this standard.
- Measures to ensure the safety of the courier the general public and the receiving laboratory
- Measures to ensure the confidentiality of patients' samples whilst in transit
- Measures to minimise delay in delivery
- Disinfection protocol following spillage
- Model rules on the type of outer container used to transport specimens.
- This policy is also subject to audit

Specimen reception

The Specimen Reception procedure RL_MP_018 includes instructions on:

- Accurate matching of request form and specimen
- Recording date of receipt
- Assigning a unique laboratory accession number
- Handling urgent samples

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- Spillage protocol
- Staff safety
- The procedure has instructions for the rejection of specimens that includes:
- The criteria for rejection of specimens.
- The recording of rejected samples.
- Notification of the user concerning rejected specimens.

Referral to other laboratories

- Very few items are referred to other laboratories.
- Maintaining a record of all samples referred.
- Recording of dispatch dates.
- Monitoring the return of reports from referral laboratories.
- Turnaround time of results from referral laboratories

5.5 Examination processes.

We aim to use procedures that are selected to meet the needs and requirements of the users, in order to make them confident that our test repertoire is designed for the maximum benefit of their patients.

Selection and validation of examination procedures

Prior to introduction, all examination procedures are validated for their intended use and the methods used and results obtained are recorded.

When examination procedures are changed so that results or their interpretation may be significantly different, the changes are explained to users prior to the introduction of the new procedure.

Examination procedures

The standard operating procedures (SOPs) for the conduct of all examinations are prepared according to the Document Preparation RL-QP-004 and Document Control and review RL-QP-008.

Procedures for the conduct of all examinations include the following:

- The purpose and scope of the examination.
- Responsibility.
- Definitions.
- Documentation (e.g. cross reference to).
- Safety considerations.
- Procedure (including limitations and QC).
- References.
- Appendices (where necessary).

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Procedural SOPs are available as hard copy in the relevant laboratory in addition to the master copy held electronically in Q-Pulse.

Refer to RL_QP_020 for details on evaluation, validation & verification procedures. Refer to RL_QP_018 for determination of uncertainty of measurement.

5.6 Ensuring quality of examination results

The laboratory has quality control procedures in place for monitoring the validity of tests performed both internally and from external sources (External Quality Assurance - EQA)

We aim to use a wide range of procedures in order to detect errors and prevent release of erroneous results. There is a comprehensive range of procedures for internal quality control (IQC) of all examinations, which verify that the intended quality is achieved.

These include:

- Records of date, source and storage of IQC material.
- A process for validation of IQC material prior to use.
- The use of recognized control organisms (ATCC & NCTC strains).
- Appropriate statistical methods.
- Acceptance criteria for results with IQC material (e.g. Assay control parameters).
- Evaluation of IQC results with corrective/preventive actions taken and recorded.

EQA

This includes participation in inter laboratory comparisons and commercial proficiency testing programs where available e.g. NEQAS. These are an important tool for demonstrating the technical competence of the laboratory. They are monitored for trends in performance which may signal an issue with the procedure and allow preventative action to be taken.

All results are recorded and any deviation from the expected result must be fully investigated and recorded as a non-conformance with the appropriate corrective and preventative action carried out. RL_QP_021 details the schemes in place including a plan for the level and frequency of participation of schemes, acceptance criteria and procedure for investigating anomalous results. This is reviewed on an annual basis at the Annual Management Review or as necessary in response to changes in methodology, equipment scope etc.

5.7 Post-examination processes

Review of results

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We aim to ensure that authorised personnel review the results of our examinations in order to ensure that patient safety is not compromised.

Storage, retention & disposal of clinical samples

We aim to comply with all regulations concerning this aspect of our service, in order to ensure that samples which must be stored are correctly handled, and samples which are marked for disposal are dealt with in accordance with the relevant legislation.

Storage, retention & disposal of clinical samples is described in procedure RL_MP_012.

5.8 Reporting of results

The report

We aim to produce reports which are clear and unambiguous and which contain sufficient information to enable our users to interpret the results for accurate treatment of their patients.

In accordance with UKAS LAB1 - Reference to Accreditation for Laboratories, URN BIS 16/25 - The National Accreditation Logo and Symbols: Conditions for use by UKAS and UKAS accredited organisations and the laboratories signed UKAS Agreement of Accreditation, the Scottish Microbiology Reference Laboratories clearly identifies all non-accredited tests on our reports for the information of our users.

Comment code - 'Test not included in UKAS Accreditation (8514) Scope' is added to define non accredited tests in accordance with the published scope.

The comment is printed on each report beneath the related result.

Reports include the following information:

- Accreditation status of test reported if not on scope
- The laboratory name and contact phone number.
- The name, date of birth and CHI number of the patient.
- The requesting individual and the source to which reports are returned.
- The specimen type and date of collection.
- Date of report.
- Examination result and reason if not carried out.
- Interpretive comments as appropriate.
- Highlighting of abnormal results.

The telephoned report

The GG&C Telephone Policy RL_MP_002 details procedure for issuing results by phone & includes:

- The circumstances in which reports may be given.
- The individuals who may issue results.
- The individuals who may receive results.
- A method of mutual identification of the patient between reporter and receiver.

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- Confirmation of correct transmission.
- The mechanism for recording the event.
- Maintaining confidentiality.
- The process for sending a follow up report.

The amended report

The procedure RL_MP_003 for issuing an amended report includes:

- The criteria for issuing amended reports.
- Authorisation level of staff able to amend reports.
- The identification of amended reports to the user.
- A process of recording the issue of an amended report.
- The reason for issuing an amended report.
- Instigation of corrective and/or preventive action, if required.
- A process for archiving amended results.

5.9 Release of results

We aim to have procedures in place to ensure that the results of our tests are accurate and are reviewed by authorized staff before release, in order to prevent any patient being endangered. Refer to use of LIMs Procedure RL_MP_028.

5.10 Laboratory information management

We aim to ensure that our data storage ensures accurate records are maintained in a form that is only accessible to authorised staff & users, in order to protect patient confidentiality.

The laboratory information system is TelePath, supported by other IT equipment for specialised tasks and it is accessed by CSW, Biomedical Scientist, Clinical Scientist, and Medical and Administrative staff. They are supported by the IT Department of NHSGG&C.

I.T. security is governed by the Data Protection Act, NHSGG&C I.T. Policy, and local SOP. Data and information are available to provide a service that meets the needs and requirements of users.

Laboratory IT Management ensures the following:

- Security.
- Access is password protected,
- Confidentiality and data protection.
- Back-up systems.
- Storage, archive and retrieval.
- Safe disposal.

References

ISO 15189:2012

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UKAS Lab 1,3,11,13,31

UKAS TP 63

UKAS TPS 47, 57

ILAC 9

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Appendix 1.

Microbiology Reference Laboratories – Management and Staffing Structure

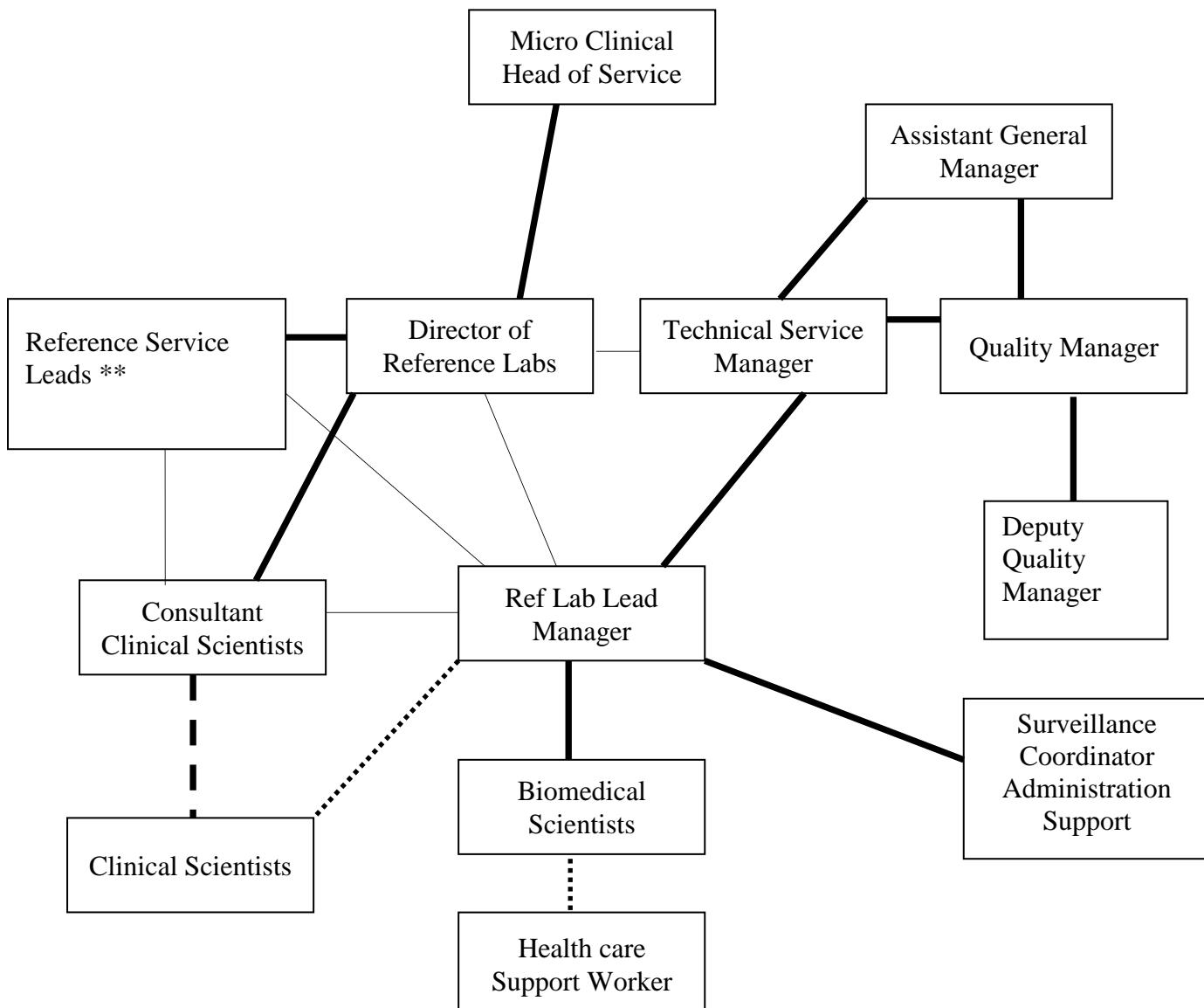
Reference Service Leads includes (see **)

Scottish Parasite Diagnostic and Reference Service

Scottish Salmonella, Shigella Clostridium Difficile and AMR Reference Service

Scottish MRSA Reference Service

Scottish Haemophilus, Legionella, Meningococcus and Pneumococcus Reference Service



Key:

- Managerial Reporting
- Research/service development/professional direction and professional development including (TURAS)
- Communication/Co-ordination/Day to day operations
- Operational management.