

**QUALITY MANUAL**

**NW GLH (Manchester & Christie) and Willink Laboratory**

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1. **PURPOSE**

This Quality Manual describes the Quality Management System for the benefit of the laboratories own management and staff, service users and inspection/accreditation bodies. Laboratory activities are carried out so as to meet the requirements of ISO 15189:2022, users, regulatory authorities and organizations providing recognition (ISO 15189 5.3.2). This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided. Although a quality manual is not required (ISO 15189 8.2.1), this document serves to provide information on policies and procedures of the laboratories.

Sections of this quality manual are arranged so that they equate with the ISO 15189:2022 standard [DOC3046]. Under the title of each standard there is a brief description of the way in which the laboratories seek to comply with the standard clause and, where information is held elsewhere, references are given to appropriate policies and/or procedures (either Trust intranet in round brackets or Q-Pulse procedures in square brackets).

1. **GENERAL LABORATORY INFORMATION**

The Genomic Laboratories (later referred to as the Laboratories) consist of:

* Biochemical Genetics Laboratory (also known as the Willink Laboratory) which comprises of Metabolic Disorders, Lysosomal Storage Disorders and Newborn Screening.
* North West Genomic Laboratory Hub (NW GLH; Manchester site) which comprises of Cytogenomics (predominantly QF-PCR and microarray tests), Specialised Cell Culture Services, Molecular Genetics for Rare Disease and Cancer (including Next Generation Sequencing panels), Specialised Rare Disease, Haemato-Oncology, and Bioinformatics.
* NW GLH (Christie site), an Oncology Cytogenetics Laboratory at The Christie Hospital. This laboratory became part of the NW GLH Manchester site on 1st June 2024.

Tests are undertaken on a variety of different tissues including blood samples, amniotic fluid, chorionic villus, post mortem samples, bone marrow, urine, skin samples, and tumour samples.

The North West Genomic Laboratory Hub (NW GLH) also includes the NW GLH Liverpool site (based at the Liverpool Women’s NHS Foundation Trust but under the legal responsibility of the Manchester University NHS Foundation Trust from 1st August 2019). Together, all these laboratories are part of the Manchester Centre for Genomic Medicine (MCGM), a directorate within the St Mary’s Hospital Managed Clinical Service, part of the Specialist Hospitals Group which is an operational unit of the Manchester University NHS Foundation Trust.

The NW GLH, in partnership with Liverpool Clinical Laboratories and Lancashire Teaching Hospital NHS Foundation Trust provides core genomic testing to the entire North West of England. This change has been brought about due to reconfiguration of genetics laboratories by NHS England to create a national NHS Genomic Medicine Service.

The Laboratories offer testing predominantly for the North-West population, but also provide some specialised services nationally and internationally. See the North West Genomic Laboratory Hub website (<https://mft.nhs.uk/nwglh/>) and the Manchester Centre for Genomic Medicine (MCGM) website ([www.mangen.co.uk](http://www.mangen.co.uk)).

The NW GLH (Manchester site) and Willink Laboratory are situated on the 6th Floor of St Mary’s Hospital (SMH) in Manchester. The NW GLH (Christie site) is located at the Christie Hospital to the south of St Mary’s Hospital and offers an Oncology Cytogenetics service. The full postal addresses are below.

**Willink Biochemical Genetics Laboratory**

Manchester Centre for Genomic Medicine,

6th Floor, St Mary’s Hospital,

Manchester University Hospitals NHS Foundation Trust,

Oxford Road, Manchester M13 9WL

**Tel:** +44 (0) 161 701 8612

**E-mail:** [mft.willink-enquiries@nhs.net](mailto:mft.willink-enquiries@nhs.net)

**Website:** <https://www.mangen.co.uk/healthcare-professionals/biochemical-genetics/>

**North West Genomics Laboratory Hub (Manchester site)**

Manchester Centre for Genomic Medicine,

6th Floor, St Mary’s Hospital,

Manchester University Hospitals NHS Foundation Trust,

Oxford Road, Manchester M13 9WL

**Tel:** +44 (0) 161 276 6122 / +44 (0) 161 276 6553

**E-mail:** NW GLH Manchester site: [mft.genomics@nhs.net](mailto:mft.genomics@nhs.net)

**Website:** <https://mft.nhs.uk/nwglh/>

**North West Genomics Laboratory Hub (Christie site)**

Oncology Cytogenetics Laboratory

The Christie NHS Foundation Trust

Wilmslow Road, Withington,

Manchester M20 4BX

**Tel:** +44 (0) 161 446 3165

**E-mail:** [the-christie.oncologycytogenetics@nhs.net](mailto:the-christie.oncologycytogenetics@nhs.net)

**Website:** <https://mft.nhs.uk/nwglh/>

1. **QUALITY MANUAL STRUCTURE AND DOCUMENTATION HIERARCHY**

Documentation is held within the laboratory quality management software database (which will now be referred to as Q-Pulse), and broadly follows a 4-tier hierarchy with this Quality Manual at the pinnacle (see figure 1). The list of documents can be viewed directly from Q-Pulse. This Quality Manual describes the Quality Management System of the Laboratories (ISO 8.2.1). It is the index volume which refers to management, laboratory, clinical and quality policies. Specific quality procedures (often with the full policy) can be found in separate documents cited in this manual. The individual working instructions (standard operating procedures, SOPs) for examination processes are not described in this manual but can be found in Q-Pulse (see section 8.3). SOPs may contain the specific quality requirements, technical requirements and working instructions for a specific procedure. In addition, Q-Pulse is used to store other records such as test validation documents, laboratory audit forms, COSHH forms, instruction manuals, meeting minutes, and maintenance/calibration (Q-Pulse Asset module).



**Figure 1: Hierarchy of Documentation for the Quality Management system.** (Image taken from the CQE Academy website.)

1. **GENERAL REQUIREMENTS**
   1. **Impartiality**

Laboratory activities are undertaken impartially. Laboratory management is responsible for and committed to ensuring impartiality. Laboratory decisions are based on objective criteria and not biased by commercial, financial, or other influences.

Although NHS England dictate which tests genomic laboratory hub’s perform via the genomics test directories, the directories are reviewed annually and updates are overseen by a Genomics Clinical Review Group (see NHS policy/procedure [here](https://www.england.nhs.uk/publication/national-genomic-test-directory-supporting-material/)). Updates are based on policy decision (e.g., NICE guidelines) or are from the assessment of applications for changes to the directories (see section 4.3).

All procurement is evaluated. Certain purchases (listed [here](https://intranet.mft.nhs.uk/content/corporate-services/finance-and-procurement/proc-and-ecommerce/proc-support); below £10K) are assessed via a prohibited discretionary spend exception approval process at Directorate level (Divisional Directorate Manager or Divisional Director). Business cases (to include options appraisals and/or quotes or identification of reasons for a waiver) are required for requisitions over £10K and are reviewed first at Directorate level and then at Managed Clinical Service level (St Mary’s Hospital Senior Management). Those at high cost or waivered require Group level approval (refer to organisation charts). Business cases can be rejected if there is threat to impartiality.

There are safeguards to ensure personnel impartiality. All new staff members are required to declare any conflicts of interest prior to commencement at the Trust. All staff members complete annual Standards of Business Conduct and Hospitality core mandatory training, which includes all staff reading the Trust Standards of Business Conduct & Hospitality Policy [CORPS 001], and staff members above agenda for change Band 6 complete a declaration of interest form (at time of completing annual training and at any point when a conflict arises). Interests to declare include shareholding, outside employment, patents, hospitality, and gifts. These forms are reviewed and monitored by the office of the Corporate Director (ISO 4.1d). Potential breaches can be reported to the hospital Chief Executive for discussion with the Corporate Director (see Trust policy) and can result in disciplinary action.

* 1. **Confidentiality**

The laboratories are responsible for maintaining the confidentiality of patient information obtained or created during laboratory processes. Processes are in place to ensure that confidentiality is maintained [DOC2051]. The laboratories do not knowingly place patient information in the public domain.

Appropriately anonymised information may be shared to publicly available reputable clinical databases/resources, only with appropriate patient consent. The transfer of laboratory test reports and patient control samples to other NHS organisations is described [DOC2051]. There is a defined process for the review of both internal and external requests for genetic data for the purposes of clinical audit, service improvement and research [DOC6193; DOC6247].

Staff members adhere to Trust and laboratory requirements to maintain patient and staff confidentiality [Trust policy IG-CP05 - Confidentiality Code of Conduct and Information Disclosure Code of Practice Policy; DOC2051]. All staff members complete an annual Information Governance core mandatory training which includes data protection legislation (Caldicott principles and NHS Confidentiality Code of Practice), subject access requests, freedom of information, record keeping, data security, and cyber security.

Contractors, visitors, and other external individuals with access to laboratory information are made aware of the requirement for confidentiality and are required to sign a declaration [MF 000 033, DOC1420].

Potential and actual breaches of confidentiality are logged as Trust level incidents on Ulysses. Deliberate or repeated conduct causing breach of confidentiality is considered misconduct behaviour and subject to disciplinary measures as per Trust Disciplinary Policy.

* 1. **Requirements Regarding Patients**

The Laboratories have the following processes to ensure patient well-being, safety and rights are the primary considerations:

1. The NHS England (NHSE) Test Directories ([here](https://www.england.nhs.uk/publication/national-genomic-test-directories/)) control the examination methods used for genetic testing, therefore patients and clinical users are unable to directly assist the NW GLH laboratories in the selection of examination methods. The test directories are peer reviewed annually (detailed [here](https://www.england.nhs.uk/genomics/the-national-genomic-test-directory/)) following a structured evidence-based review process implemented by NHSE to ensure they are up to date with the latest advances in science and technology. These reviews include applications for changes to the directories, evaluation of policy decisions, and horizon scanning. Genomic test evaluation working groups were set up to support directory updates; membership of the groups includes scientists, clinicians, health economists, and patient & public representatives. Applications for updates and changes to the test directories can be made to NHSE by any stakeholders (see NHS policy/procedure [here](https://www.england.nhs.uk/publication/national-genomic-test-directory-supporting-material/)). The Willink Laboratory is allied to the Willink Metabolic Unit ([here](https://www.mangen.co.uk/healthcare-professionals/clinical-genomic-services/the-willink-metabolic-unit/)) which allows close collaboration with consultants, specialist nurses and dieticians.

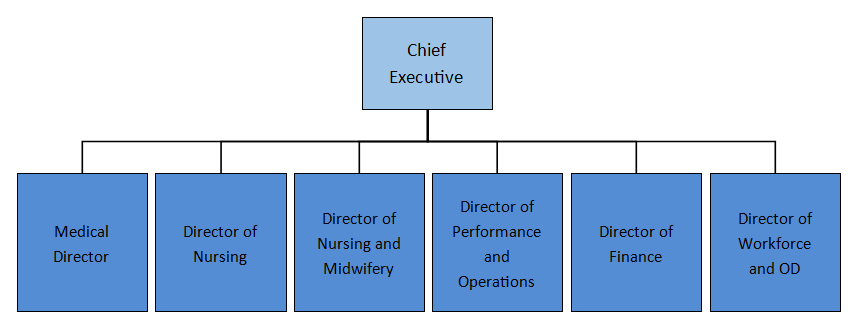
Various regular multi-disciplinary team meetings are held, with laboratory staff in attendance, allowing discussion and interpretation of results with clinical user groups. Annual user surveys also capture important clinical user feedback and suggestions on services provision and testing. Patient feedback can be submitted via the procedure available on the NW GLH website ([here](https://mft.nhs.uk/nwglh/quality/queries-feedback-and-complaints-procedure/)) or Willink website ([here](https://www.mangen.co.uk/healthcare-professionals/manchester-genetic-diagnostic-laboratory/quality/)), but due to the complex nature of genetic testing, patients do not assist in the interpretation of genetic results.

1. For GLH testing, NHSE National Test Directories provide examination method information and testing criteria, available on the NHS website and via the NW GLH website ([here](https://mft.nhs.uk/nwglh/test-information/rare-disease/genomics-tests/)). Expected turnaround times are available on the laboratory NW GLH website ([here](https://mft.nhs.uk/nwglh/quality/laboratory-test-service-turnaround-times/)). Testing information and expected turnaround times for the Willink Laboratory can be found in their laboratory handbook ([here](https://www.mangen.co.uk/healthcare-professionals/biochemical-genetics/) and as DOC1134). Testing information and expected turnaround times for the Christie Oncology Laboratory service can be found on their website and in their laboratory user guide ([here](https://www.christie.nhs.uk/patients-and-visitors/services/pathology/oncology-cytogenetics#:~:text=Oncology%20cytogenetics%20at%20The%20Christie,of%20leukaemia%20and%20other%20tumours.) and as DOC6453). Price lists are available to users on request [DOC2157, DOC2017].
2. Examinations offered by the NW GLH laboratory are dictated by NHSE National Test Directories. Eligibility and appropriate testing are specified in the directories and managed via sample receipt processes, trained duty scientist staff and duty scientist procedures. Willink examinations are reviewed periodically in senior management meetings. For all laboratories, sample numbers and testing are monitored at monthly quality meetings and formally trended as part of annual management review.
3. Incidents resulting in actual patient harm or that could have resulted in harm are recorded at Trust level on Ulysses system [DOC1006]. High impact learning review or assessments (HILR/A) may be required for review by SMH Governance Team depending on the severity of the incident and level of harm. As part of this process the service user is informed of the incident and patient duty of candour would be considered and actioned where necessary by relevant senior or clinical staff. Records of actions would be recorded via Q-Pulse/Ulysses records.
4. Laboratory policies for training and competency, and Trust mandatory training schedule ensures all staff are competent to handle patient samples and testing appropriately, with due care and respect. The NW GLH also provides a local education session on ‘Ethics in Genetic Testing’ and Trust HTA training is provided for relevant staff to ensure respectful treatment of human samples [staff induction and training]. Trust values (section 5.5) are reviewed annually at appraisal by all staff and at quarterly lab meetings.
5. Consent information for testing is stated on the NW GLH website ([here](https://mft.nhs.uk/nwglh/documents/consent/)) and in the Willink Laboratory Handbook [DOC1134] and Christie Oncology Cytogenetics User Guide [DOC6453] and in laboratory procedure [DOC2051]. The Laboratories infer that consent has been obtained by way of receipt of a patient sample and completed referral form. Standard consent forms are available on the websites for standard testing. Specific consent is required for NW GLH whole genome sequencing, also available via the NW GLH website.
6. Storage facilities to maintain availability and integrity of samples and records are provided and maintained [DOC1464, DOC1279].
7. Laboratory enquiries to the NW GLH Manchester site are received and triaged by administrative staff via a central email account and telephone system. Enquiries to the Willink Laboratory are received via reception, admin, or the duty scientist. Enquiries to the Christie Oncology Cytogenetics Laboratory are received via the laboratory administrator. Contact details and information relevant to patients and service users are available on the websites.

Patients can make a subject to access request via the Trust Medico Legal Department ([here](https://mft.nhs.uk/the-trust/other-departments/medico-legal-department/)).

1. Mandatory training schedule, laboratory induction, training and competency policies and engagement with Trust values ensure the rights of patients to care are upheld and free from discrimination.
2. **STRUCTURE AND GOVERNANCE REQUIREMENTS**
   1. **Legal Entity**

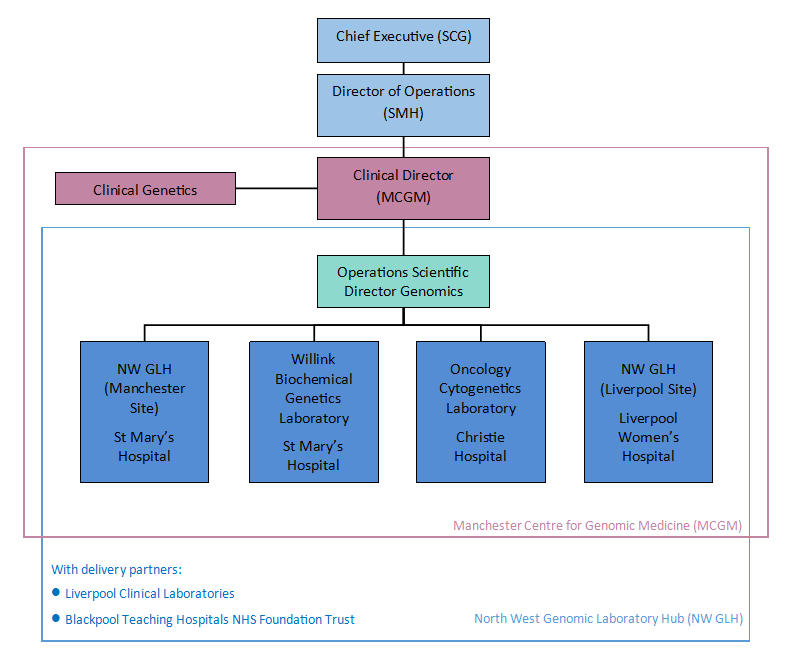
The Laboratories are part of the directorate of the Manchester Centre for Genomic Medicine (MCGM) within the St Mary’s Hospital which (together with Royal Manchester Children’s Hospital and the Manchester Royal Eye hospital) is part of the Specialist Hospitals Group, one of 6 Clinical Groups within the Manchester University NHS Trust (MFT). MFT is legally responsible for the activities of the laboratories (ISO 15189 5.1). The top-level Specialist Hospitals Group organisation (Manchester University NHS Trust) is shown in figure 2 below.



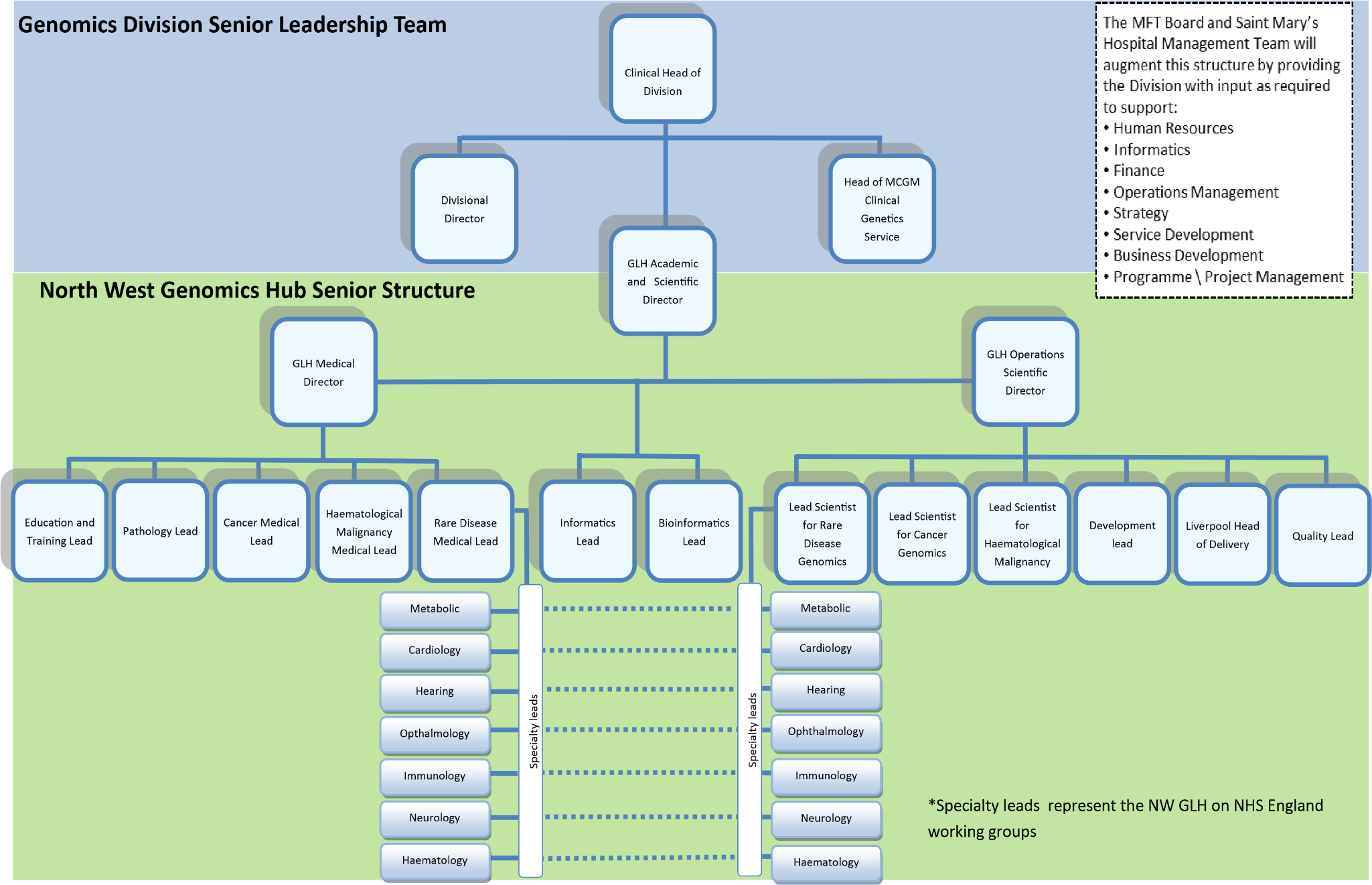
**Figure 2: The Host Organisation.** The Manchester University NHS Foundation Trust (MFT) Clinical Group.

The internal organisational relationships are shown in figure 3. The Manchester Centre for Genomic Medicine and the Laboratories (incorporating the NW GLH Manchester site, NW GLH Liverpool site, Christie Oncology Cytogenetics Laboratory, and the Willink Biochemical Genetics Laboratory) have a defined management structure.

1. St Mary’s, The Manchester Centre for Genomic Medicine and Laboratory management structure.



1. The NW GLH management structure



**Figure 3: The relationship of (A) the Laboratories to the Host Organisation and (B) the NW GLH to the Host Organisation.** Manchester University NHS Foundation Trust (MFT); St Mary’s Hospital (SMH); Manchester Centre for Genomic Medicine (MCGM); Specialist Hospitals Clinical Group (SCG). Note that the GLH Operations Scientific Director also has responsibility for the Willink Laboratory and is therefore described throughout this document as the Laboratory Director. Note also that the Christie Oncology Laboratory is managed by the Lead Scientist for Haematological Malignancy.

* 1. **Laboratory Director**

The Director of the Laboratories (also the GLH Operations Scientific Director and described within this document as the Laboratory Director) is a Consultant Clinical Scientist and has the responsibility for the services provided by the Laboratories supported by a Senior Management Team of consultant and Principal Clinical Scientists. This is currently Dr Emma Howard. The duties and responsibilities of the Laboratory Director are documented below. These include professional, scientific, consultative/ advisory, organisational, administrative, educational, and quality matters relevant to the services offered by the laboratories. The ongoing competence of the Laboratory Director is assessed through successful appraisal, NHSE assurance assessment and UKAS assessment. The Laboratory Director can delegate duties and/or responsibilities to other qualified personnel but maintains the ultimate responsibility for the overall operation and administration of the Laboratories. The deputy Laboratory Director, Victoria Stinton, or other Consultant Clinical Scientists take overall responsibility in the absence of the Laboratory Director [MP000 008].

The Laboratory Director (and designate/s):

* Ensures the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results (Senior Management Team, Scientists)
* Communicates with external agencies including accreditation and regulatory agencies (Senior Management Team or Quality Management Team as appropriate)
* Provides budget and financial management (Senior Management Team)
* Ensures appropriate staff numbers (Senior Management Team including Technical Managers)
* Ensures implementation of the quality policy and manual (Quality Management Team)
* Defines, implements, and monitors key performance standards and quality improvement (Senior Management Team, Quality Manager and Quality Management Team)
* Provides professional development programmes and other opportunities for staff (Training Team)
* Ensures a safe laboratory environment (Senior Management Team, Health & Safety Team)
* Ensures laboratory risks are identified and actioned, and that risk processes are effective (Senior Management Team, Divisional Quality & Safety Committee, Quality Management Team)
* Selects referral laboratories and monitors quality of service (Senior Management Team and Quality Management Team)
* Selects and monitors laboratory suppliers (Technical Managers)
* Addresses complaints and suggestions (Quality Manager)
* Plans and directs research (Senior Management Team, Development Team)
* Ensures a contingency plan for essential services (Quality Management Team, Senior Management Team including Technical Managers)
  1. **Laboratory Activities**

Accredited laboratory activities are documented on the UKAS schedule of accreditation document published on the UKAS website [here](https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9865-Medical-Single.pdf). Updates/additions to activities are made to UKAS via extension to scope applications. There are no POCT activities performed under the UKAS schedule. Laboratory price lists [DOC2017, DOC2157] provide a list of the laboratory activities.

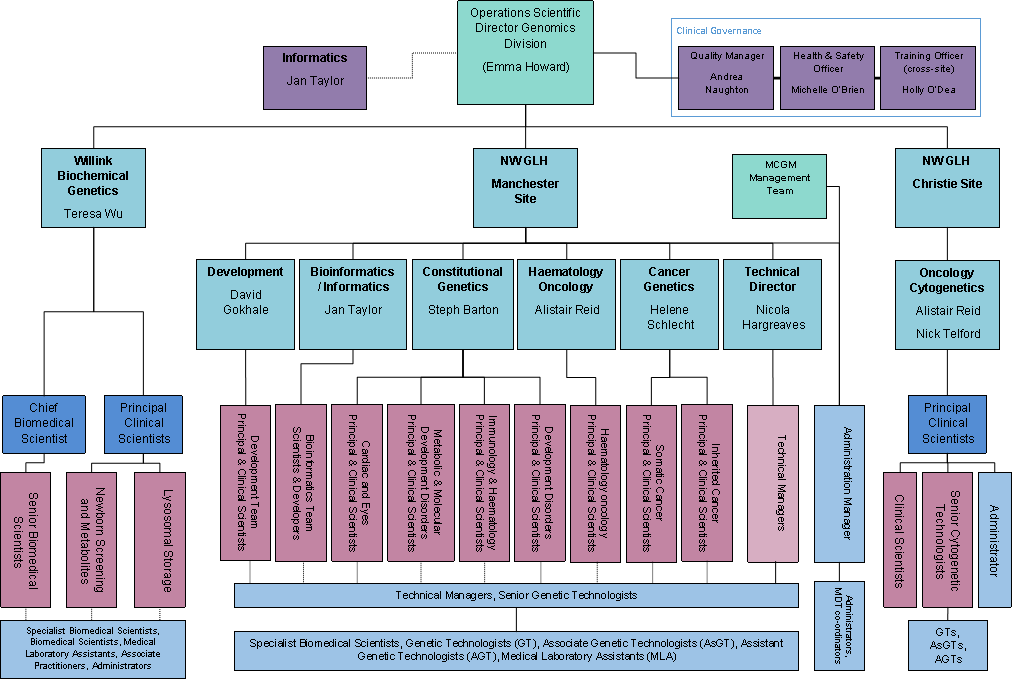
Laboratory activities are carried out in such a way to meet the requirements of the ISO 15189:2022 standard, service users (clinicians & patients), regulatory authorities and organisations providing recognition (including UKAS, NHS England, Care Quality Commission, and MFT, LWH and Christie Trusts), with relevant policies and procedures in place.

The Laboratories offer direct advice and support (via telephone and email) to service users for laboratory activities such as general test requirements (including choice of test, sample type, frequency of requesting the same test), test reports (including interpretation of results and test limitations), or any concerns they may have about the service [DOC2077]. Clinical advice and test interpretation is only given by appropriately trained scientific staff. General information (choice of tests, clinical indications, sample types, acceptance requirements) is also supplied on the respective websites. Failure of a sample to meeting acceptability is reported directly to the clinician via a report (or by telephone if urgent).

* 1. **Structure and Authority**
     1. **General**

The Laboratories consist of the NW GLH (Manchester site and Christie site) and the Willink Laboratory, governed by the Manchester Centre for Genomic Medicine (MCGM), a directorate within the Specialist Hospitals Group (see section 5.1). The organisation of staff is represented in the organisational chart (Figure 4). The Laboratories are managed by the Laboratory Director with site specific sections led by Consultant Clinical Scientists or a Technical Director (NW GLH Manchester). The Technical Director supports the technical team at the Christie site. Each site is broadly divided into scientific and technical teams; all are supported by administrative staff. Sections are sub-divided into Teams supported by Principal Clinical Scientists or Technical Managers. Cross professional cover is provided by key members of staff. There are dedicated Informatics and Bioinformatics teams that support the NW GLH.

All staff and their roles (including staff at the GLH Liverpool site) are documented in the Genomics Laboratory Staff (NW Region) Roles and Responsibilities document [DOC2072]. The specific roles and responsibilities of the Quality management team are described [DOC488].

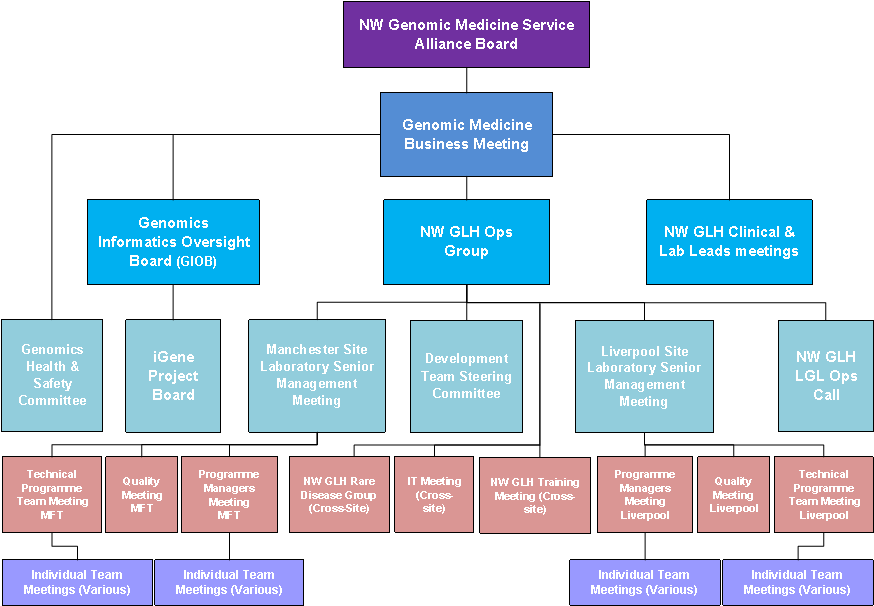


**Figure 4: The organisation within the Laboratories. This includes the NW GLH Manchester site, NW GLH Christie site and Willink Laboratory.**

The Laboratories have different methods and means for communicating with staff including meetings, an all-staff laboratory meeting, newsletters, e-bulletins, lunchtime seminars, and staff suggestions via a forum, whiteboards, Q-Pulse register and new NW GLH Education & Training suggestion board ([here](https://padlet.com/chriswatt/nwglh-education-training-suggestion-board-hz0m437reaq2nldb)). Minutes for many meetings are available on Q-Pulse. Quality Management meetings are distributed to all staff members. Dashboards are available on shared network drives.

The Laboratories communicates with stakeholders via the websites, letters, complaints, and user satisfaction surveys. Stakeholders are informed of any significant changes to services.

The NW GLH meetings are summarised in DOC4969 (and figure 5). The Christie site holds a Christie laboratory staff meeting and representatives attend appropriate NW GLH meetings. The Willink Laboratory holds Operational Management meetings and laboratory staff meetings.



**Figure 5: The organisation of NW GLH meetings.**

Regular top-level meetings include:

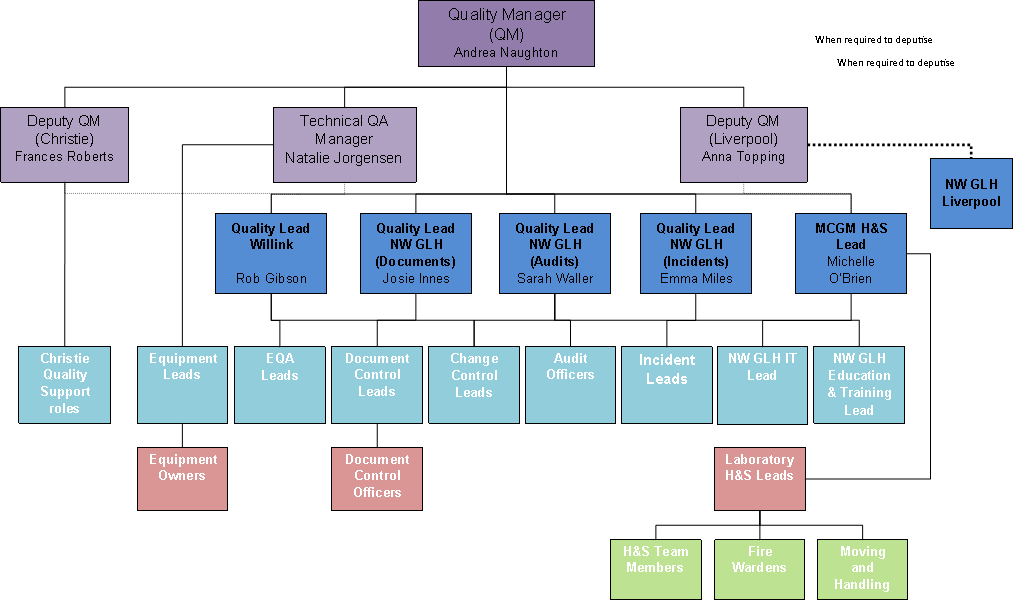
* The **MCGM Genomic Medicine Business Group** meets monthly, attended by the Clinical Head of Division, Divisional Director, NW GLH Operational (Laboratory) Director, Head of MCGM Clinical Genetics Service, MCGM Governance Lead, MFT Communication and HR representatives.
* The **North West GLH Operations Group** meets monthly, attended by the NW GLH Operational Director, Liverpool Head of Service / Deputy Director, Directorate Manager, Section Lead Scientists / Consultant Clinical Scientists, Team Leads / Principal Clinical Scientists, Technical Managers, Development Team Lead and NW GLH Quality Lead (Quality Manager).
* The **Willink Biochemical Genetics Operational Management Team** meets monthly attended by Head of Willink Biochemical Genetics, Section Leads and deputies, and Chief BMS (also Quality Lead for Biochemical Genetics). Notes of the meetings are circulated to members of the team and appropriate actions taken.
* The **Genetic Medicine Quality & Safety Committee** meets monthly, attended by the MCGM Governance Lead, Quality Manager of the Laboratories, Deputy Quality Managers (representing NW GLH Liverpool and Christie sites), Laboratory Representative for Biochemical Genetics, Chief Nurse for MCGM (and Clinical Quality Manager), Clinical Representative for Biochemical Genetics, Clinical Research Representative, Office Manager for Clinical Genetics, Clinical Audit Lead, MCGM Health & Safety Lead and Genetic Counsellors’ Representative. Minutes of these meetings are circulated to members and appropriate actions taken. Minutes are also made available to members and are held by the PA to the Clinical Lead.
* The **Genetic Medicine Health & Safety Committee** meets every quarter attended by the Health & Safety Lead (Michelle O’Brien) and representatives from clinical, laboratory and research teams. Any issues relating to Health and Safety are discussed. Minutes are taken [DOC1163].
* The **Quality Management Team** meets monthly attended by the Quality Manager, Technical Programme Quality Assurance Manager, Deputy Quality Manager (Christie site), Quality Leads, Education &Training Lead, Incident Lead, Document Control Lead, MCGM Health & Safety Lead, Audit Lead, EQA Lead, IT Lead, Technical Director, and Technical Managers. Notes of the meetings are circulated to members of the team and appropriate actions taken. Minutes are made available to all members of staff via Q-Pulse [DOC1172].

In addition, all Willink staff members [DOC729] and Christie staff members [DOC6554] meet monthly. Due to the large size of the other laboratory areas the Technical Programme Managers meets every month with Technical Team Managers [DOC5771]. Specific Technical Team and Clinical Scientist Team meetings are held on a regular basis and minutes are made available to all members of staff via Q-Pulse.

* + 1. **Quality Management**

There is an appointed Quality Manager who, with support of with Senior Management and the Quality Team, is responsible for overseeing the implementation, development, maintenance, and improvement of all quality management activities across all laboratory sites. They ensure integration of this system into the Trust governance and risk management systems. They report directly to the Laboratory Director on the performance and effectiveness of the quality management system and any need for improvement. The Quality Manager also promotes awareness of the needs and requirements of service users by providing guidance to staff in seminars and meetings.

The current post-holder is Dr Andrea Naughton. There is also a Deputy Quality Manager (Frances Roberts; who manages quality at the Christie Oncology Cytogenetics Laboratory) and a Technical Quality Assurance Manager (Natalie Jorgensen, who manages technical quality assurance for the NWGLH). There are currently four Quality Leads who can also deputise for the Quality Manager: Josie Innes (Cytogenomics), Emma Miles (Constitutional Genomics), Sarah Waller (Cancer Genomics) and Rob Gibson (Biochemical Genetics). All aspects of quality are supported by teams of staff. The organisation of the Quality Management Team is shown in figure 6 below.



**Figure 6: Organisation of the Quality Management Team.**

* 1. **Objectives and Policies**

The Laboratories are committed to providing a high-quality service that considers and aims to meet the needs and requirements of its clinical users and patients, commitment to good professional practice and compliance to ISO 15189 Standards. The Quality Policy [DOC1018] sets out the commitments and objectives of the Laboratories and is reviewed biennially. The Quality Policy reflects the Trust values (we are compassionate, we are curious, we are collaborative, we are open & honest, and we are inclusive) and the Trust objectives (to work with partners to help people live longer, healthier lives, to provide high quality, safe care with excellent outcomes and experience, to be the place where people enjoy working, learning and building a career, to ensure value for our patients and communities by making the best use of our resources, and to deliver world-class research & innovation that improves people’s lives). The quality policy and other laboratory policies referenced within this document are implemented and accepted at all staff levels via Q-Pulse.

Laboratory objectives for all levels of the NW GLH laboratory organisation and activities are considered at an annual strategy meeting attended by senior management. The NW GLH Scientific Operations Director, Head of Service, Deputy/Quality Manager define measurable quality objectives of the laboratory (with timelines and responsibilities) and are responsible for ensuring that plans are made to meet these objectives. The Willink Laboratory senior team similarly define their measurable quality objectives at their Senior Management meeting. The Laboratories quality objectives are available to all members of staff on Q-Pulse [DOC1343], and their progress is reviewed regularly. The annual management review determines whether the objectives have been successfully completed and provides an opportunity for revising objectives, plans, and the functioning of the quality management system. The management reviews can be found on Q-Pulse [DOC1020].

The Laboratories have a quality improvement framework for change management [DOC6029] to ensure planned changes to the management system are standardised and implemented appropriately.

Performance indicators used to evaluate and monitor key aspects of pre-examination, examination and post-examination processes are defined [DOC1017].They are proactively reviewed at monthly quality meetings. Test turnaround data is reviewed monthly in Quality Management and Team meetings. NW GLH test turnaround is reviewed by NHS England quarterly.

* 1. **Risk Management**

The Laboratories identify risks of harm to patients from examination processes and other laboratory activities (ISO 15189 5.6a) via different processes [DOC6562], including:

* Validation/verification of processes prior to implementation of new or changed methods [DOC2063, DOC2010].
* Errors, incidents and other non-conformances or trends in non-conformances [DOC1006].
* Non-conformances or observations from internal audit activity [DOC1288; DOC5317]
* Risk assessments [DOC2931]
* Patient/service user complaints [DOC1187]
* Staff suggestions/complaints [DOC1187]
* Quality improvement projects [DOC6029]
* Equipment reviews of end-of-life, end-of-service-life (support) or repeated failures
* Discussion of services at laboratory meetings

When potential failures or risks are identified, the process is risk assessed and appropriate control measures are put into place to reduce the risk and, if necessary, actions are undertaken to reduce/eliminate the risk (ISO 15189 5.6a). If a risk impacting patient service/care cannot be mitigated sufficiently, users will be informed as appropriate (e.g., service delivery issues affecting turnaround time or the need to redirect testing to another centre as part of business continuity plans).

Risks are raised, assessed, actioned and monitored using the Trust procedures for recording risks [Trust ‘Risk Management Framework and Strategy’ Policy, Trust [risk guidance](https://intranet.mft.nhs.uk/content/patient-safety-1/risk-management-resources), and DOC5705]. The Trust uses a web-based risk register (Ulysses, Safeguard) to document, control, action and escalate risk. Laboratory risks are raised on Ulysses with oversight from the Laboratory Director (ISO 15189 5.6b). Risks are reviewed at laboratory, divisional and hospital level depending on the risk score (ISO 15189 5.6b). Risks are graded based on likelihood and consequence; priority is given to high scoring risk.

1. **RESOURCE REQUIREMENTS**
   1. **General**

See sections 6.2-6.8 below.

* 1. **Personnel**
     1. **General**

Laboratory activity/performance and staffing needs are monitored and managed by the Scientific Operational Director and senior management team to ensure sufficient and appropriate staffing. The Laboratories use relevant Trust policies and procedures issued by the Trust and HR/Recruitment Office for staff recruitment and selection. The Trust vision and values are included in recruitment in published job adverts and reviewed annually at staff appraisal. See section 8.1 regarding communication to staff on the importance of following the management system and meeting the needs of service users and patients.

Each member of staff has a job description and contract of employment complying with current legislation and provides terms and conditions of service. There are manager procedures to ensure that new starters receive relevant information and support [DOC3178, DOC6215, DOC5911].

All new staff participate in the Trust induction programme (described [here](https://intranet.mft.nhs.uk/content/corporate-services/mandatory-training)) including employee health & well-being, pension & payroll and mandatory training modules (evidenced on ESR). Trust mandatory training includes information governance and code of conduct. In addition, the laboratories have their own induction procedures and forms which are held on Q-Pulse including:

* DOC775 Induction Policy and Guide
* DOC772 New Starters Induction Checklist
* DOC2854 Health & Safety Induction Checklist
* DOC5908 Ethical Issues in Genomic Testing Presentation
* DOC6174 Quality Induction
* DOC968 Willink Training Logbook Local H&S and General Laboratory Functions

Other training specific to the section and position in which staff will be working is also given using the appropriate documents (logbooks) which are available in Q-Pulse (see section 6.2.2).

* + 1. **Competence Requirements**

All staff are suitably qualified to take up their position with appropriate education, qualifications, experience, and skill. Required qualifications, and desired skill and experience are documented in the person specification of the job description for each role (ISO 6.2.2a). Generic template job descriptions are held locally in the HR folder on the Genetics shared drive. Each member of staff has a job description and contract of employment with MFT providing clear terms and conditions of service. Staff recruitment takes place following the Trust recruitment procedures. All staff employed at Clinical Scientist and Biomedical Scientist grades are HCPC registered. Ongoing HCPC registration is monitored via a scheduled audit. Genetic Technologists with sufficient experience are directed towards the voluntary state registration register.

There is an education and training policy [E&T000 019]. Training is provided for all staff which includes training of specific work processes, health & safety requirements, quality management system, information management system, ethics, and confidentiality [e.g., DOC2854, DOC2850, DOC841, DOC5908]. New staff are only trained by personnel who are deemed both competent in the procedure, task, or process, and capable as a trainer.

The laboratory process for assessing initial competency and monitoring ongoing competency is documented [DOC840]. It also describes requirements for reassessment and/or retraining. Various competency forms (training logbooks) specific to laboratory activities covering pre-examination, examination, and post-examination processes, and quality and management tasks relevant to staff roles and responsibilities are available on Q-Pulse and are used to record training and competence. Competency is assessed (e.g., via direct observation of skills, verbal assessment of technical knowledge, review of training and experience, assessment of EQA scheme performance, and/or assessment of problem-solving skill) and authorised by appropriate personnel. Staff do not work unsupervised until they have been formally deemed competent on any given procedure, task, or process (ISO 6.2.2b). Once trained and deemed competent, all individual staff have responsibility for the output and quality of their own work.

Continued/ongoing competency or performance is monitored through day-to-day activities (e.g., oral assessment, examination of work records, or witness examination audits) and is reviewed annually at appraisal via a review of competency form [DOC840].

The NW GLH has an Education & Training Lead providing oversight and organisation of training needs across the GLH. There are also NW GLH Scientific Educator Leads and a Willink Laboratory Training Officer.

* + 1. **Authorisation**

The Laboratories have processes to authorise personnel to perform specific laboratory activities including:

* Selection, development, modification, validation, and verification of methods
* Review, release, and reporting results
* Use of laboratory information systems

The Laboratories have training and competency documentation for laboratory activities (including the review, release and reporting of results) and considers a signed competency document for individually named staff to fulfil the requirement for authorisation to perform the specified activity. The use of laboratory information systems is embedded into training and competence of laboratory activities (e.g., booking in referrals, reporting of results), and therefore authorised in the same way.

For the NW GLH, test method selection and testing criteria eligibility is regulated by NHSE Test Directories for rare disease and cancer; therefore, there is no process for the selection or development of examination procedures/methods. For the Willink Laboratory, the senior management team select laboratory methods.

The selection and authorisation of staff to perform method introduction or modification, and validation or verification is considered and agreed by senior management staff and is based on staff experience, knowledge, skills, and capacity. Authorisation is also part of the Laboratories framework for quality improvement, whereby proposed changes to a laboratory system/process are reviewed and assessed by senior management and must obtain authorisation to proceed, if approved [DOC6029].

* + 1. **Continuing Education and Professional Development**

The ongoing training and education needs of trained staff are identified through appraisal. Each member of staff has an annual appraisal with their line manager to ensure continued competency, review job description and staff performance, review laboratory objectives, set personal objectives and identify learning/training needs for continued staff development, as required. This uses the Trust appraisal documentation and guidance which is available on the Trust intranet (a toolkit accessed via the Learning Hub [here](https://intranet.mft.nhs.uk/content/corporate-services/mft-learning-hub)). The Trust provides appraisal training. A copy of the completed appraisal documentation, which includes an agreed personal development plan, is returned to staff to store electronically in staff folders on the shared drive or hard copy in a personal file. A record of appraisal date for all staff is used to monitor compliance via the Quality & Safety Committee.

Senior staff take part in the RCPath CPD scheme. All other scientific and technical staff maintain their own CPD records. The Health and Care Professions Council (HCPC) performs a CPD audit on registered staff at registration renewal; staff must maintain good records of training and development to provide material to HCPC, if requested.

There are Trust education courses as part of organisational development and training (provided via the Kallidus Learning Hub), laboratory seminars/ education sessions are arranged weekly (accessible to all staff), and other opportunities available for staff to enable continued education and professional development. Participation in national meetings is encouraged, and feedback from these meetings is presented at cross site education sessions.

The NW GLH is accredited by the National School of Healthcare Science in partnership with the Workforce Development sub-committee of the ACGS as a training centre for Clinical Scientists and Practitioners. The Willink Laboratory is approved by the Institute of Biomedical Science to provide pre-registration BMS training.

* + 1. **Personnel Records**

Individual job descriptions, contracts of employment and copies of qualification certificates are held centrally by MFT Workforce Planning. Records of absence are managed via the Absence Manager application (managed by MFT Workforce Planning Department). An occupational health record is held by the Occupational Health Department within the Trust.

There is a laboratory personnel file for each staff member either as a restricted electronic file (NW GLH/Willink; see DOC3178) or as a locked hardcopy paper file (Willink Laboratory). Personnel files are created and managed by the Administration team (GLH) or the Chief BMS (Willink). Files should include employment information, signed contract, job description, local induction form, appraisal forms, training, and competency forms. It is the managers responsibility to ensure that copies of employment information, contract, and job description provided by MFT Workforce Planning are given to the personnel file manager at the start of employment to create a personnel record [DOC3178]. It is also the managers responsibility to ensure that the induction form and ongoing records of training, competence (which includes authorisation), and appraisal are also passed to the personnel file manager for inclusion in personnel records. Ongoing HCPC registration is monitored via a scheduled audit.

Records of educational/professional qualifications, training, and competence (initial and ongoing) for staff are also held and maintained by each staff member in CPD (training/competence) folders.

* 1. **Facilities and Environmental Conditions**
     1. **General**

The Laboratories provide a safe working environment for staff and visitors (Trust Health & Safety Management Arrangements Policy) [DOC2021]. Procedures exist to ensure guidance and safety of visitors [DOC1420] and contractors [MF 000 033].

The Manchester Centre for Genomic Medicine (MCGM) occupies the 6th floor of St Mary’s Hospital [DOC24]. Samples for the NW GLH Manchester and Willink Laboratory are delivered to the MCGM Sample Reception [DOC4854]. The Trust holds a contract with Sodexo to provide building and environment maintenance, cleaning, and some equipment maintenance and service.

The Oncology Cytogenetics Laboratory occupies a 2nd floor area of The Christie Hospital, above the Wilmslow Road entrance. Samples are delivered to the laboratory via the Pathology sample reception [DOC6378]. MFT has an SLA in place with The Christie Hospital in for maintenance of estates and facilities.

Each site has a safe working environment, which is functional and well maintained, and in accordance with relevant legislation. Office areas are cleaned by contractors and there are staff cleaning schedules for laboratory areas. Separate office and laboratory space is provided with defined areas. Temperature/humidity dependent areas and equipment are monitored; Kelsius monitoring at MCGM [DOC4211] and paper records at the Christie laboratory site [DOC6419]. Curatorship [DOC2031, DOC4884] and stock control [DOC2108, DOC6369] ensures that laboratory areas and equipment are clean and operational. Regular Health & Safety audits are carried out.

* + 1. **Facility Controls**

Access to the two sites is limited to authorised staff only using proximity cards (managed by the Trusts) to ensure safety, quality, and confidentiality. Laboratory information systems which contain patient information are access controlled using usernames and passwords and appropriate access/permission levels (see 7.6.3) [DOC3115].

Standard operating procedures and separated working areas for certain laboratory activities mitigate cross-contamination of samples/products where applicable to ensure quality and safety. For example, office only and laboratory only areas, pre-PCR and post-PCR, clearly defined and separate cell culture rooms, use of biological safety cabinets and fume hoods. Waste disposal streams are controlled [DOC2064, DOC6553]. The Health and Safety Policy [DOC2021] and COSHH [DOC2325, DOC6485] ensures that staff are aware of safety procedures, facilities, and devices, including maintenance.

Safety facilities and/or devices are provided and regularly checked/tested to ensure they are functional and in a reliable condition, for example, fire alarm and extinguishers, gas alarms, first aid boxes and eye wash stations, and electrical safety checks. Regular Health & Safety audits are also carried out to check and monitor environmental conditions and facilities which include estate condition, lighting, noise, ventilation, electrical safety, safety devices etc.

* + 1. **Storage Facilities**

Facilities exist within the Laboratories for storage of materials in accordance with national legislation and to ensure safety and/or continuing integrity. Storage, maintenance, and disposal procedures (as appropriate) are described for documents and records [DOC1279], clinical material [DOC1464], chemicals and hazardous substances [DOC2021, DOC2022, DOC2023, DOC1507], equipment [DOC2107, DOC6428], reagents and consumables [DOC2025, DOC6369, DOC6382], and waste material [DOC2064, DOC6553]. There is dedicated onsite storage facilities for flammable reagents, acids & solvents, where required. Secure offsite document storage to maintain retention of NW GLH records for appropriate timescales is provided by Restore [MP 000 080].

* + 1. **Personnel Facilities**

Facilities are provided for staff [DOC473] including secure locker or drawer space, toilets, shower facilities (SMH), basic catering facilities (beverage bays and/or a staff room with a supply of drinking water), access to meeting rooms, and access to the hospital cafeteria, cafes, and shops. Other facilities are provided as appropriate including computer facilities and safety equipment (PPE).

* + 1. **Sample Collection Facilities**

The Laboratories do not offer facilities for patient sample collection.

* 1. **Equipment**
     1. **General**

The Laboratories have policies and procedures for the appropriate selection, procurement, installation, acceptance (validation, verification, or acceptance testing), handling, transport, storage, use, maintenance and disposal or equipment [DOC2107]. Procedures are carried out by appropriate authorised staff [DOC2107]. Assessment and selection of new equipment is carried out by senior and principal members of the Laboratories, in consultation with the Technical Programme Manager/Director or Chief Biomedical Scientist (Willink). Procurement of equipment and services are authorised by senior management. Equipment is overseen by the Technical Team Leads and Senior BMS. Senior Technologists and Senior BMS manage the day-to-day running of equipment.

* + 1. **Equipment Requirements**

The Laboratories have access to equipment required for correct performance of laboratory services. Each item of equipment is registered in Q-Pulse with a unique identification code. Use of NW GLH Christie site laboratory equipment by Christie Pathology Partnership staff is managed via a service level agreement. The use of NW GLH Manchester site equipment by Manchester University staff is managed via a working agreement [DOC5888]. The Laboratories maintain equipment and replace as needed. For high-cost equipment, when funding is not available for replacement when it is approaching end of life, the equipment is placed on the Trust capital expenditure request list and a risk is raised on the Risk Register.

* + 1. **Equipment Acceptance Procedure**

The Laboratories have policies and processes for equipment acceptance. This includes validation or verification as required [DOC2063], the acceptance of new equipment for use [DOC2107, DOC3125], and the acceptance of existing equipment into use following maintenance or repair [DOC2107, DOC4212]. These processes include whether the equipment conforms to specified acceptance/performance criteria or calibration data [DOC2063, DOC2107]. When possible, new equipment is evaluated and tested prior to selection and purchasing to ensure it meets specifications.

* + 1. **Equipment Instructions for Use**

Where possible, equipment is locked down to prevent unintended adjustments. For certain equipment instrument/software, input and/or adjustments are required on each run. In these cases, the requirements are indicated in documented processes with input checks in place.

Equipment is only operated under supervision for staff in training. On completion of training, staff are authorised and deemed competent to operate equipment alone.

Equipment instructions for use (ISO 6.4.4c) are provided as standalone documents on Q-Pulse and/or are incorporated in individual procedures detailing the correct day-to-day use and maintenance (written with consideration of manufacturer recommendations). Where equipment is used outside manufacturer recommendations it is validated for use [DOC2063].

* + 1. **Equipment Maintenance and Repair**

Appropriate equipment external maintenance programmes and procedures for internal maintenance are in place. Whenever equipment is found to be defective, it is taken out of service and clearly labelled until it has been replaced and verified or repaired and accepted back into use [DOC2107; DOC3125].

External maintenance programmes are carried out by Sodexo or other contracted reputable companies. Decontamination is completed as required. External companies are provided with suitable space and PPE (if required). The Laboratories use ISO 17025 accredited calibration services when appropriate [DOC3172].

* + 1. **Equipment Adverse Incident Reporting**

Errors and incidents directly involving equipment are reported as a non-conformance on Q-Pulse via the Non-Conformances and/or Equipment & Assets modules [DOC1006, DOC2107, MP 000 147]. Adverse incidents and accidents are reported to the manufacturer/supplier and (if appropriate) to the Medicines and Healthcare products Regulatory Agency (MHRA).

* + 1. **Equipment Records**

For each item of equipment (including hardware and software) there is an asset record in the Equipment & Assets module of Q-Pulse [MP 000 147]. Each record includes a unique identification code, asset type, manufacturer/supplier, model, serial number, relevant dates, location, and availability. Separate sections provide information (as appropriate to the equipment) on service contract, maintenance activities, comparison testing, non-conformances, and calibration. These records are kept indefinitely. Manufacturer instructions, manuals, maintenance or calibration records, acceptance for use, comparability forms and other relevant information can be attached to the record.

* 1. **Equipment Calibration and Metrological Traceability**

Laboratory equipment that requires calibration and traceable calibration is specified [DOC3172] and considers whether the equipment is used for quantitative or qualitative methods. There is a procedure for ensuring calibration of relevant equipment [DOC2107]. All calibrations are performed by external suppliers, who are ISO 17025 accredited to ensure metrological traceability of calibrations when required. Verification of the required accuracy uses performance criteria for each equipment type [DOC3172]. Calibration is recorded in the equipment record in Q-Pulse. Correction factors are not used. Equipment failing calibration is repaired or removed from use.

* 1. **Reagents and Consumables**

The Laboratories have policies and processes for the management of reagents and consumables [DOC3386]. These include selection and procurement [DOC2106], receipt and storage [DOC2025, DOC2023, DOC6369], reagent acceptance testing [DOC3387, DOC6361], inventory management and stock control [DOC2108, DOC6369, DOC6382], and the management of manufacturer instructions for use [DOC3386, DOC3387]. When a consumable that can affect laboratory processes is sourced from an alternative manufacturer it is acceptance tested [DOC3386, 9.1].

Reagents and consumables are received and stored according to manufacturer instructions with refrigerator, freezer, and ambient temperature monitoring in place where appropriate (ISO 6.6.2). The Christie laboratory is the only laboratory that does not directly receive reagents and consumables. These are delivered to the Pathology laboratory central receiving point via the Christie Receipt and Distribution Centre and are appropriately stored prior to transfer. The Pathology laboratory completes a regular audit of the Christie Receipt and Distribution Centre to ensure adequate storage and handling of goods to prevent damage and deterioration.

Errors and incidents directly involving reagents or consumables are reported as a non-conformance on Q-Pulse via the Non-Conformances and/or suppliers modules [DOC1006]. Adverse incidents and accidents are reported to the manufacturer/supplier and (if appropriate) to the Medicines and Healthcare products Regulatory Agency (MHRA).

* 1. **Service Agreements**

Each request for testing is considered an agreement with the service user. The requirements of service users are indicated on the North West Genomic Laboratory Hub (<https://mft.nhs.uk/nwglh/>) website and MCGM ([www.mangen.org.uk](http://www.mangen.org.uk)) website. Specific instructions are given on some referral forms, export forms, the Willink Laboratory Handbook [DOC1134] and the Christie Oncology Cytogenetics User Guide [DOC6453].

Genomic testing in England is commissioned via NHS England as directed by National Test Directories, therefore there are minimal NW GLH regional service level agreements (SLA’s) outside of this arrangement (usually SLAs to support approved research studies).

Where specific contracts for medical laboratory services are established, these follow an agreed procedure [DOC1192]. These service level agreement contracts are documented on Q-Pulse [Management & HR>Service Level Agreement (SLA)]. Any new services are designed and developed with appropriate resources and staffing and validated appropriately. Variations to SLA’s are required in writing and must be accepted and signed by both parties before a new contract is issued. Review of SLA’s forms part of the annual management review.

There is an agreement between the NW GLH Manchester and Liverpool sites for service processes [DOC5634] and an agreement between the NW GLH Manchester and University of Manchester regarding use of NHS laboratory equipment [DOC5888]. No laboratory offers point of care testing.

* 1. **Externally Provided Products and Services**
     1. **Selecting and evaluating referral laboratories and consultants**

The laboratories ensure that externally provided products and services that affect laboratory activities are suitable. These include equipment (see section 6.4-5), reagents and consumables (section 6.6), referral laboratories (see below) and MFT managed or sub-contracted services (Sodexo, Restore, Ricoh, software providers, EQA providers etc.). The laboratories do not use advisory or interpretation services from external consultants.

* + 1. **Referral Laboratories and Consultants**

The NW GLH Manchester and Willink Laboratory periodically sends samples to external laboratories and has a procedure for the evaluation, selection, and monitoring of referral laboratories [QP 000 008]. All exported samples are recorded on the appropriate LIMS database. There are laboratory procedures in place for sending (exporting) samples to referral laboratories [DOC2166, LP 000 007, LP100 007, LP130 009, LP160 035,MP000 072].

The majority of NW GLH Manchester referral laboratories are laboratories of other Genomic Laboratory Hubs providing specialist genomic testing not offered by the NW GLH but specified by NHSE (listed [here](https://www.england.nhs.uk/genomics/genomic-laboratory-hubs/)). For all referral laboratories (listed in the review of referral laboratories, QF 000 006), requirements are indicated with the onwards referral (original referral and export form). The GLH requests (via an export letter) that Genomics reports from the referral laboratory for exported referrals are sent directly to the clinician (with a copy sent to the GLH for reference) to enable the management of urgent results. Report copies are attached to the LIMS database. Samples are exported by the GLH on behalf of external and internal (Clinical Genetics) referrers [DOC3341]. The periodic monitoring of referral laboratories is documented [QF 000 006]. The Christie Laboratory does not use referral laboratories.

The Willink Laboratory uses referral laboratories for Biochemical Genetics tests not available at the laboratory. There is a process for export to referral laboratories and a list of referral laboratories is maintained [DOC2166]. Biochemical Genetics reports received from referral laboratories on exported samples are copied onto the database and the original report sent out to the clinician (although some labs also send a copy of the report directly to the clinician, particularly for urgent results). Report copies are attached to the LIMS database [DOC2166]. The periodic monitoring of referral laboratories is documented [DOC3082].

* + 1. **Review and Approval of Externally Provided Products and Services**

Major suppliers of equipment, reagents, consumables, and services are listed and recorded on Q-Pulse in the Supplier Module and scheduled for a review every 2 years [DOC475]. The Laboratories have a documented procedure for the selection and purchasing of equipment, reagents, and consumables [DOC475]. There is also a procedure for ordering supplies and consumables [DOC2106]. The Laboratories record any problems with equipment as nonconformities in the Q-Pulse Equipment & Assets Module and any problems with reagents, consumables, and services as error logs and/or Supplier nonconformities.

1. **PROCESS REQUIREMENTS**
   1. **General**

All procedures (pre-examination, examination, and post-examination) are carried out by trained competent (authorised) staff who follow pre-defined validated procedures. Procedures have been assessed for clinical risk, health and safety, and measurement uncertainty consideration, with measures implemented (as appropriate) to mitigate identified risks (e.g., independent transfer, label or witness checks, use of personal protective equipment, internal quality control specification, analysis data checks, and report checks).

The Laboratories identify risks and opportunities for improvement in examination processes via many routes including incident reporting and management, equipment & reagent management, performance monitoring (e.g., assay and culture failure rate, turnaround time, low resolution rate), EQA participation, staff competency assessment and internal audit schedule (e.g., vertical audit/sample journey).

Any risks are addressed by the appropriate personnel and controls or actions put in place to mitigate the impact and potential for recurrence. We ensure risks are reduced to an acceptable level. Where risks remain, they are reported on the risk register, monitored, and reviewed and actions put into place. Risks on the register are only closed when the level of residual risk is deemed at an acceptable level by laboratory management, such that it would not impact patient care, and therefore residual risk would not usually need to be communicated to clinical users. If a risk impacting patient service/care was in the process of risk management and not mitigated sufficiently, users would be informed as appropriate (e.g., service delivery issues affecting turnaround times).

See also 5.6 Risk Management, 8.5 Actions to address risks and opportunities for improvement, and 8.6 Continual Improvement.

* 1. **Pre-examination Processes**
     1. **General**

Documented procedures are in place for all pre-examination processes and are available to all staff via the Q-Pulse document module. Pre-examination information relevant to clinical users is also available on websites and in user guides. There is a policy and procedure for referral to the Laboratories for diagnostic testing [DOC4123].

* + 1. **Laboratory Information for Patients and Users**

Information for patients and users (ISO 5.4.2) is available:

* Willink information: MCGM website ([www.mangen.org.uk](http://www.mangen.org.uk)) and laboratory handbook ([here](https://www.mangen.co.uk/healthcare-professionals/biochemical-genetics/) and as DOC1134).
* NW GLH Manchester site information: NW GLH website (<https://mft.nhs.uk/nwglh/>)
* NW GLH Christie site information: NW GLH website (<https://mft.nhs.uk/nwglh/>) and laboratory user guide on The Christie website ([here](https://www.christie.nhs.uk/patients-and-visitors/services/pathology/oncology-cytogenetics) and as DOC6453).

Information held on the websites or user guides includes the location, contact details and operating hours for the Laboratories, types of tests offered (including turnaround times) and sample requirements (container type, quantity, transport, acceptance policy), requirements for patient consent and complaint process. Price lists are available on request [DOC2017, DOC2157, DOC2289].

* + 1. **Requests for Providing Laboratory Examinations**

Each request for testing is considered an agreement with the service user. Requests for most examinations are made using an appropriate referral form available via the websites [DOC4900, LF160 001, DOC512]. Specific forms are required for certain Willink services [DOC4245], GLH cancer services [DOC4112, DOC4147, DOC4230, DOC4388, DOC5640, DOC5932-DOC5938, DOC5942], GLH Haematology Oncology [DOC5775], Christie Oncology Cytogenetics [DOC6455], and GLH specialised rare disease services [DOC4544, DOC5640, DOC6004].

The requirements for sample and minimum identifier criteria are stated on the website and on laboratory referral forms, including patient identification on the request and sample, identification of and contact information of the referrer, and identification of the test request with clinical details. The Laboratories communicate with users to clarify requests, where necessary.

Where a verbal request for testing is received, confirmation in writing is required (email or completed referral form). Procedures exist for dealing with incomplete information that may affect onward processing of samples [DOC1563].

* + 1. **Primary sample collection and handling**

The Laboratories are not directly involved in the preparation of patients for sample collection (ISO 7.2.4.2a), collection of specimens (ISO 7.2.4.1) or in any special or invasive procedures to obtain samples (ISO 7.2.4.4). However, they do offer guidance on pre-collection activities including:

* Patient information that is required on both the sample and the referral form
* Sample requirements – sample type, sample amount, and collection container
* Acceptance/rejection criteria associated with missing information and sample requirements
* Sample transportation – containment, packaging, and timing of delivery

This information is available on referral forms, websites, or in user guides (ISO 7.2.4.2).

The risk to patient outcome due to rejection by a laboratory of a particular sample is considered on a case-by-case basis; in particular, samples of an urgent or precious nature may be accepted for processing where they ordinarily would not (see section 7.2.6.2) [DOC1563]. The Laboratories periodically review unsuitable samples (those which do not meet sample acceptance requirements regarding sample volume, collection device, and labelling) via scheduled audits (and are considering the possibility of more regular monitoring and review at quality meetings but may require development of the LIMS).

It is the responsibility of the referring clinician to obtain informed consent for testing from the patient or their representative (ISO 7.2.4.3). Informed consent is inferred by receipt of a sample accompanying a written request for testing (usually as a referral form); consent information is available on the websites or in user guides. Full details for the policy and procedures are given in Policy and Procedures for Consent and Confidentiality [DOC2051].

* + 1. **Sample Transportation**

The Laboratories do not control or manage the transport of specimens (ISO 7.2.4.5). However, packaging guidance [EO 000 033, DOC1419] and any specific transport requirements to ensure the integrity of the sample (e.g., sample temperature, timeframe for delivery, and sample container) are provided on the websites or in user guides. There are processes in place for the safety of laboratory staff and appropriate notification if the integrity of a received sample has been compromised during transport [DOC1417]. Errors and incidents relating to sample acceptance or transport are recorded in Q-Pulse (and as Trust incidents if appropriate), and monitored for trends [DOC1006].

* + 1. **Sample Receipt**

There are procedures for sample receipt and booking in for the NW GLH Manchester [DOC4854, LP000 019, DOC4676, LP160 005], Christie [DOC6378, DOC6397], and Willink [DOC4868, DOC4117] laboratories. Key documents include procedures relating to identification of the patient on the sample and referral form, sample acceptance, and prioritisation of urgent samples. There are procedures for the triaging of referrals for testing by Duty Scientists for the NW GLH Manchester [DOC4826, DOC4827, DOC4828, DOC4829, DOC5755], Christie [DOC6543, DOC6365] and Willink [DOC4868, DOC4117]. There are some additional standalone procedures for sample acceptance [LP000 026, DOC6050, DOC6552], inappropriately labelled samples [DOC1563], high risk samples [DOC2044, DOC6471/DOC6490], and leaking samples [DOC1417]. LIMS are used to record patient and sample information, triaged test information and relevant dates (including date stamp of receipt), and have appropriate change logs. Sample acceptance includes exemptions for processing urgent or precious samples [DOC1563, DOC6552, DOC4117] (ISO 7.2.6.2).

* + 1. **Pre-examination Handling, Preparation and Storage**

The Laboratories have relevant procedures for pre-examination sample handling (see 7.2.6) and appropriate facilities for securing samples that avoids deterioration, loss, or damage [DOC1464].

There is no time limit for requesting additional examinations on samples in long term storage, such as extracted DNA, cDNA, and cryogenically stored cells. For short-term storage (e.g., cytogenetic cell suspension preparations (6 months), RNA (6 months), bloodspot cards (5 years)) requests can be actioned within a certain time frame [DOC1464]. Other primary samples are disposed of once adequately prepared (blood) or once the report has been issued [DOC1464]. If a stored sample is found to be inadequate on request for additional testing (e.g., DNA quantity/quality), a new sample is requested.

Sample stability and times frames between collection and sample receipt are specified on websites, user guides and/or on relevant referral forms. The Laboratories do not unnecessarily delay pre-examination processes that could impact the stability of the analyte (e.g., RNA, plasma amino acids). The time between sample collection and receipt is considered for samples known to be affected by prolonged transit.

* 1. **Examination Processes**
     1. **General**

The selection of examination methods for the NW GLH is regulated by NHSE as Test Directories for rare disease and cancer, therefore, the NW GLH does not have a process of selection or review of examination procedures for clinical utility. The tests given in these directories are peer reviewed annually by designated working groups (detailed [here](https://www.england.nhs.uk/genomics/the-national-genomic-test-directory/)). Laboratory senior management review and evaluate impact of the new revisions of the directories, when available and where necessary, prior to implementation. For the Willink Laboratory, the selection and evaluation of procedures is determined by patient need and the availability of appropriate technology; the senior management team periodically review the examinations provided by the Willink Biochemical Genetics laboratory in their Operational Management Team meetings.

All new examination procedures are verified or validated for their intended use prior to implementation by following laboratory procedure [DOC2063, DOC2010, DOC5803]. Validation and verification are part of the quality improvement system ([DOC6029]. Verification is achieved by acceptance of manufacturers’ data and by in-house confirmation of performance characteristics. Validation is achieved by a more robust methodology to extensively examine the procedure performance characteristics. Any significant changes to examination procedures are revalidated and reported to relevant users prior to implementation if necessary. Any significant changes to manufacturers’ kits are reverified prior to their use. Performance specifications based on the intended use of the examination procedure and impact on patient care inform the requirements of the validation/verification. These can include measurement trueness, accuracy, and precision (repeatability and intermediate precision), measurement uncertainty, analytical and/or diagnostic specificity/sensitivity, interfering substances, limits, and measuring interval. Measurement uncertainty is evaluated to ensure robustness of quantitative values output for patient results. Validation and verification reports are appropriately approved via Q-Pulse by the Laboratory Director or a member of the senior management team responsible for the service.

Standard operating procedures, validation/verification records, and other relevant documentation is controlled and available to staff via Q-Pulse (see section 8.3). Personnel follow established procedures and the identification of those carrying out activities as part of the examination process are recorded (e.g., LIMS, worksheets, and reports). The laboratories do not provide point of care testing (POCT).

* + 1. **Verification of Examination Methods**

Refer to section 7.3.1, DOC2063 and DOC2010.

* + 1. **Validation of Examination Methods**

Refer to section 7.3.1, DOC2063 and DOC2010.

* + 1. **Evaluation of Measurement Uncertainty (MU)**

The laboratories accept the principle and requirement for measurement of uncertainty within our scope of practice. MU has been considered for all processes and applied, where applicable, within the laboratory activities. This includes the evaluation of MU and critical measurements in SOP’s, assessment of MU in validation/verification, and the use of MU in setting monitoring ranges (e.g., temperature control alerts). DOC3172 provides guidance on the measurement of uncertainty in assays and measuring instruments, and documents MU review and performance specifications for measuring instruments. MU in assays is reviewed at SOP document review. Where there are specified assay MU values, these can be made available to users on request.

* + 1. **Biological Reference Intervals and Clinical Decision Limits**

For quantitative tests (and certain semi-quantitative tests) biological reference intervals or clinical decision values are determined based upon test validation and quoted in the standard operating procedure. Where appropriate, reference intervals are quoted on the patient report. Reference intervals or clinical decision values are reassessed. When changes are made to examinations and this impacts on associated biological reference intervals and clinical decision limits, users are informed.

* + 1. **Documentation of Examination Procedures**

Examination procedures (standard operating procedures; SOPs) are available to all staff in English and are controlled via the Q-Pulse database (held in the relevant diagnostic section of the active document register). These procedures are reviewed regularly by examination and vertical audit and changed in the light of objectives and new methods as appropriate. When changes are made to examinations and this impacts on the interpretation of results, this are explained to users.

The NW GLH utilises checklists at the end of certain full SOPs that can be printed at the time of the examination and stored as a worksheet or discarded following testing. Both the Willink Laboratory and the Christie Laboratory have folders of controlled hard copies of SOPs that can be used within laboratory areas. The folders contents are updated when an SOP is updated, and the folders reviewed regularly for obsolete documents.

Templates are available for general documents [DOC842] and for examination procedures [DOC2739, DOC2889]. Examination procedure templates include provision for the addition of information on the purpose, principle, performance characteristics, sample types, equipment & reagents, internal quality control, risk assessment & COSHH, measurement uncertainty and calibration requirements, reference intervals & interferences (where appropriate), data analysis & interpretation and procedural steps.

* + 1. **Ensuring the Validity of Examination Results**
       1. *General*

The Laboratories have procedures for monitoring the validity of results including internal quality control (IQC) processes [DOC6563] and participation in external quality assessment [DOC1564]. Where appropriate, trends and shifts in IQC are monitored.

* + - 1. *Internal Quality Control (IQC)*

The Laboratories have a policy [DOC6563] and processes for monitoring the validity of results using internal quality controls. Examination processes are IQC risk assessed [DOC6563]. The risks and measures are documented in examination standard operating procedures. Certain examination procedures have separate processes for the evaluation of IQC metrics, e.g., Willink Unity for all tests [4090], MiNT QC application for Next Generation Sequencing [DOC6327], Genome Studio for arrays [DOC6124, DOC4976]. Internal quality control results or assay data metrics are recorded on relevant worksheets and/or LIMS or in Unity (Biochemical Genetics; ISO 7.3.7.3e).

Examination procedures use appropriate controls and have defined acceptability criteria to ensure quality and validity of patient results. Controls include internal assay standards, reference materials, assay controls, positive/negative controls, and blanks, as appropriate, and with consideration of the clinical application, to ensure quality of patient results. The selection of test positive IQC material also takes into consideration the stability and formulation to ensure that it mimics a patient sample as much as possible (ISO 7.3.7.2b).

In certain high-risk circumstances, to ensure accuracy of the result, duplicate samples are analysed, or analytical results are confirmed using either a different methodology or the same methodology on a different subsample of the primary sample. The quality and accuracy of analytical data is ensured by analysis, reporting and authorisation procedures.

Most genetic tests do not give a measurable numerical value and controls will produce an expected qualitative outcome (positive or negative) therefore there is no ability to check for trends and shifts in IQC material (ISO 7.3.7.2e). Where there are exceptions, measurement uncertainty is considered for the acceptability criteria and data is reviewed against expected values on every run (ISO 7.3.7.2f). For Biochemical Genetics tests that produce measurable numerical values, ICQ material is used within reference ranges - at normal concentration levels, and clinically relevant concentration levels where suitable material is available (ISO 7.3.7.2b). IQC measurements are recorded in Unity and are regularly evaluated for trends and shifts [DOC4090]. The Laboratories do not perform high throughput quantitative testing. Therefore, there is no concern regarding changes to calibration or IQC material within the same day/run.

Standards and controls supplied with manufactured reagent/assay kits are used where available, following manufacturer instructions for use and validation. Kits are accepted via the acceptance of use procedure [DOC3387]. Genetics in-house validated tests or commercial kits provided without controls use appropriate retained positive/negative patient samples that are fit for their intended purpose and clinical application on each run (ISO 7.3.7.3a3/b/d). Certain genetic tests do not require the use of IQC materials, e.g., karyotyping. Biochemical Genetics use third party IQC material when manufacturer supplied control material is not available.

Where results do not meet expected outcome or meet acceptance criteria, the data is reviewed; if all acceptance criteria are not met the results are rejected and the run repeated (ISO 7.3.7.3g). Where limited acceptance criteria are met results are reviewed by senior scientific staff, and results may be reported with suitable provisos.

* + - 1. *External Quality Assessment (EQA)*

The Laboratories monitor performance of examination methods by comparison with result of other laboratories and have procedures for the participation and evaluation of performance in these comparisons [DOC1564, DOC697]. Where possible, the Laboratories participate in recognised External Quality Assessment schemes (GenQA, UKNEQAS, EMQN, ECFN, ERNDIM and CDC) with preference given to UKAS accredited schemes. The Laboratories participate in schemes relevant to the laboratory tests they provide as well as those relating to pre-examination processes (e.g., DNA extraction and quantification) and post-examination processes (e.g., genotyping and interpretation). Where there are no specific schemes available, the Laboratories will participate in generic technical EQA schemes or a suitable alternative, such as an exchange of samples with other laboratories. Samples are processed by the same personnel who routinely perform the procedures being assessed and are (as far as practicable) processed in the same manner as other patient samples, ensuring an evaluation of the end-to-end process.

Records of scheme participation and a summary record of the performance in EQA schemes and other comparisons is kept on secure account servers (NW GLH Manchester [here](file:///S:\Genetics\Mol_Shared\all.users\EQA), NW GLH Christie [here](file:///Z:\Quality%20Management%20docs\GenQA), and Willink [here](file:///\\xcmmc.nhs.uk\OrgData\Willink\BG-QMS-%20Key%20documents%20not%20on%20Qpulse%202012%20onwards\EQA)), which allows for trend analysis. EQA activity and performance is communicated to staff at laboratory meetings and summarised in the Annual Management Review. Scheme results are received by EQA Leads/Officers and reviewed by the service leads. Deductions and actions (where applied to the scheme) and poor performances are recorded as non-conformances in Q-Pulse and are appropriately investigated, including an assessment of whether the finding could impact diagnostic patients. If found to impact patients, results are reviewed and amended, and users informed.

* + - 1. *Comparability of Examination Results*

All examination procedures are carried out on a single specific site. Individual tests generally use the same equipment and methods for all patients. Where multiples of the same instrument exist (e.g. NGS sequencers. TMS) or different testing methods (e.g., ddPCR and Cobas) can be used as part of standard assay processing, these variations are incorporated into test validation [DOC2063] where possible. To provide assurance that the interchangeable use of either equipment (e.g., thermal cyclers, genetic analysers, NGS sequencers, TMS) or test methods does not impact the validity of results, comparability studies are undertaken by direct comparison of patient, control, IQC material, or EQA results [DOC4815]. Currently, no equipment is used interchangeably for quantitative results that would produce clinically significant differences and impact on biological reference ranges and clinical ranges.

* 1. **Post-examination Processes**
     1. **Reporting of Results**
        1. *General*

The Laboratories have defined policies and processes for the accurate, clear, and unambiguous reporting of results:

* NW GLH Manchester – General policy & processes [DOC2066]; Molecular Genetics [MP 000 014]; Cytogenomics [MP000 024, DOC2630]; WGS [DOC4852, DOC4470]
* NW GLH Christie – policy [DOC6386] and processes [DOC6362]
* Willink Laboratory – General policy & processes [DOC2066, DOC463, DOC1042]

For the NW GLH, reports are tangible letters containing the results. For the Willink Laboratory, ‘reports’ are records of the results transferred from Beaker into the MFT Trust-wide electronic patient record (EPR; EPIC Hive). Reports include all information necessary for the interpretation of the result (where an interpretation is not given within the report).

There are standalone documents for checking of results [MP000 007, DOC2726] and for interpretation or classification of results [DOC3074, DOC4934, DOC5989, DOC2608, DOC4934, DOC6076].

Laboratory reports are currently created through 4 separate LIMS: (i) iGene or (ii) the Molecular Genetics laboratory database (DLIMS) for NW GLH Manchester tests, or (iii) EPIC Beaker for Biochemical Genetics tests or (iv) SHIRE for Christie Oncology tests. The DLIMS is under decommissioning with all tests soon to be managed in iGene. There are processes for the use of LIMS to enter, write, and authorise report results using iGene [DOC4227, DOC6036, DOC6114, DOC4224], DLIMS [DOC4898], Beaker [DOC6003], and SHIRE [DOC6367, DOC6363]. Reports are accessible through LIMS and all associated information is retained [DOC1279, MP 000 104].

There are procedures for informing users of delays, dependent on the urgency and patient impact [DOC2066, DOC463, DOC6362]. If appropriate, the requesting clinician is informed of the delay with an estimated timeframe for when the result will be available. If the delay impacts on critical clinical management decisions, senior staff will decide whether the sample should be immediately sent to another laboratory for testing. Business contingencies may be triggered appropriately by senior management [DOC6001, DOC2809, DOC5433, DOC6349].

* + - 1. *Result Review and Release*

NW GLH analytical data is analysed independently by two appropriately trained staff members, the second being a registered Clinical Scientist. For the Willink Laboratory, dependent on the test, there is at least one registered Clinical Scientist or Biomedical Scientist to review patient results data. Concordance of analytical data, review of internal quality measurements (as appropriate to the test), and review of clinical information ensures accurate results. Where appropriate previous results are reviewed. All examination results are authorised before release by appropriately trained staff [DOC2066, MP 000 014, DOC463, DOC2077, DOC6386].

Reports are usually released to service users electronically by email or uploaded to patient databases (e.g., EPIC Hive, HODS) but hardcopies can be released by post [DOC2065, DOC463, DOC6386]. There are strict criteria regarding who can release verbal results and to whom [DOC2065, DOC6386]. Policies and procedures are in place to ensure that reports are handled and released confidentially [DOC4869, DOC463, DOC6104, DOC4869, DOC2806].

* + - 1. *Critical Results Reports*

Urgent tests (with short turnaround targets) are prioritised for testing, review, and release [DOC463, DOC6362]. Where Willink metabolic test results are critical for the care of the patient they are reported verbally to the on-call Metabolic Consultant [DOC463].

* + - 1. *Special Considerations for Results*

Critical and urgent verbal results may be simplified results but are always followed up by an authorised report [DOC463, DOC2065, DOC6386]. A record of the verbal result is added as a note on the appropriate LIMS. The Laboratories do not issue preliminary reports.

Laboratory reports with genetic results are not communicated directly to the patient. Only certain Willink monitoring tests are appropriately viewed by patients on MyMFT (MyChart) which is linked to EPIC Hive.

There is a process of data request review [DOC6193, DOC6247] which ensures that when results of laboratory examinations are requested for use in statistical analyses, risk to patient privacy and confidentiality is considered and mitigated.

* + - 1. *Automated Selection, Review, Release and Reporting of Results*

The Laboratories do not have any systems for automated selection, review, release and reporting of results.

* + - 1. *Requirements for Reports*

Report content conforms to the requirement of ISO 15189 and other relevant best practice guidelines. Reporting procedures include details on the requirements for reports [DOC2066, MP 000 014]. These requirements include patient identification, laboratory identification, referrer identification, date of receipt or collection, report date, sample type, identifiable pagination, examination(s), method(s) (where relevant), and result(s), identification of person authorising the result (or readily available when needed). When appropriate to the referral and examination(s) performed, reports will also include supporting information (e.g., concordance with other results), comments (e.g., other examinations in progress), units of measurement, biological reference ranges, clinical decision limits, measurement uncertainty, test specifications and limitations, whether the test is part of a research programme or ISO 15189 accredited.

* + - 1. *Additional Information for Reports*

It is not necessary for patient care to include the time of sample collection on laboratory reports. The time of report release is not consequential, but the date of report authorisation/release is readily available on the report or from the appropriate LIMS if required.

Where an examination is performed by a referring laboratory in its entirety on behalf of the NW GLH laboratory, the laboratory requests that the report is sent directly to the referring clinician (with a copy sent to the referring laboratory). For routine send away tests from the Willink Laboratory (e.g. CSF neurotransmitters), the report is returned from the referral laboratory to the Willink Laboratory and attached to Beaker in its entirety for viewing on EPIC Hive. Therefore, the laboratories do not incorporate or alter referring laboratory reports in any way. Where parts of examinations are performed by a referral laboratory, this is indicated on the report (e.g., WGS by Illumina and Genomics England).

When applicable, reports include interpretation of results and cautionary comments or explanatory notes including where sample quality can potential impact the clinical value of the result (e.g., prenatal maternal contamination, low resolution chromosomes), discrepancies when examinations are performed in different location (e.g., MRD testing), advice relating to further testing requirements, genetic risks to family members, result trends/changes over time (e.g., MRD testing and relapse/remission status), or sample suitability (with respect to rejected samples). Such comments may form part of the report template or as report ‘notes’ added when specifically required.

* + - 1. *Amendments to Reported Results*

Amended reports, when required, are issued to the service user using defined procedures [DOC2048, DOC6362, DOC6386]. These procedures include the requirement to state on the new report that it is an amended report, why it has been amended, the date of amendment, and reference the original report and/or date of issue (as appropriate). For NW GLH reports, the original and amended reports are retained. For Willink records in EPIC Hive, the amended result is appended to the original record.

* + 1. **Post-examination Handling of Samples**

The Laboratories have procedures that define sample retention times and storage conditions [DOC1464]. Procedures conform to the recommendations of the Royal College of Pathologists [MP000 057]. Stored samples are uniquely labelled and stored appropriately. DNA, cDNA, and cryogenically stored cells are extremely stable and are retained indefinitely to allow for additional tests. Other samples are stored according to retention guidelines and disposed of appropriately. When the request for an additional test on a stored sample is received, the suitability of sample is determined (e.g., stored DNA quantity/quality or viability of cells following recovery from cryogenic storage). If the stored sample is found to be inadequate a new sample is requested.

* 1. **Nonconforming work**

Nonconforming work is when any aspect of examinations, laboratory activity, or service provision does not conform to its own procedures, quality specification/criteria, or user/patient requirement. Procedures are in place to ensure that non-conformances (errors and incidents) are managed effectively [DOC1006, DOC1508]. Examples of where no-conformances can arise include processes, equipment, reagents, suppliers, internal quality control, and IT failures. Nonconforming work also arises from other sources such as internal/external audits and surveys [DOC1288], complaints [DOC1187], external quality control, and performance indicator non-compliance (e.g., turnaround times) [DOC1017].

All nonconformances are raised, managed, reviewed, and approved via the Q-Pulse non-conformance module by appropriately trained and authorised staff (7.5a) [DOC1006]. Nonconformances that impact staff and patients (e.g., actual staff harm, patient harm through misdiagnosis/misreporting, inappropriate patient testing, extended disruption/risks to services/equipment) are raised as Trust incidents, managed by the senior quality management team, and reviewed at Divisional Quality & Safety meetings [DOC1006]. Specific patient safety incidents are reported externally [DOC1006, DOC3109].

Immediate (remedial) and long-term (corrective) actions from non-conformances are specified in Q-Pulse (see also section 8.7). Actions are based on the findings from the non-conformance investigation (7.5b). The investigation (recorded in Q-Pulse) considers the significance of the non-conformance, risk of recurrence, extent of risk to work, risk to patients, and impact on patients involved (7.5b).

Non-conformances with a risk to patient harm are escalated to a Team/Programme Lead to agree appropriate actions and acceptability of work e.g., isolating/withholding samples, reports, or halting services (7.5c). Consideration is made to the potential for other patients to be affected (work performed prior to the identification of the non-conformance) (7.5d). A decision to resume service, processing and/or release of results, following necessary investigations, is made by an appropriate senior staff Team/Programme Lead or above (7.5e,g). Where incorrect results have been released, the referring clinician is notified, and an amended report issued (7.5f).

* 1. **Control of Data and Information Management**
     1. **General**

The Laboratories use laboratory data management systems and software applications which generate a large amount of electronic (computerized) data. The policies and procedures relating to electronic data security, access, back-up of data, storage, archive, and retrieval are documented [DOC3115]. The policies and procedures relating to security, access, storage, and disposal non-computerized data are documented [DOC1279].

* + 1. **Authorities and Responsibilities for Information Management**

The NW GLH IT Service Manager and Willink Chief BMS are responsible for the maintenance and administration of respective locally managed IT systems and software. Some systems are managed centrally by MFT IT department (e.g., Microsoft 360 including Outlook email, HIVE/Beaker). The administration of systems and software is documented [DOC3115]. There are several main laboratory patient information systems. The Willink uses EPIC Beaker [DOC6003] and the MFT IT Department provide access to the system. The NW GLH primarily uses iGene and local administrators provide access to the system [DOC4201]. Staff members are allocated defined levels of access to electronic systems and software (including LIMS) as appropriate to their laboratory role and/or grade.

* + 1. **Information Systems Management**

There is a documented policy and procedures for information management [DOC3115]. Laboratory information management systems (LIMS) and software used for the collection, processing, recording, analysis, reporting and storage of patient test data is appropriately verified prior to use and following a significant software upgrade [DOC3115; DOC2063, section 6] by appropriate personnel. Where appropriate, changes to information systems are recorded as quality improvement projects on Q-Pulse [DOC6029]. As a minimum, the verification will be documented on Q-Pulse.

Documented procedures on the use of LIMS [DOC4201, LP 000 107, DOC1499, DOC6003]. and other software are available on Q-Pulse. Staff members are appropriately trained in their use and their training documented.

Laboratory computer hardware and networks are supported by the MFT IT department. As an NHS organisation, the Trust adhere to industry standards, best practice, and continuous improvement; dedicated cyber security teams are embedded within the Informatics departments.

All Trust personal computers and laptops are password protected. All staff members have their own username and password credentials. LIMS are password protected and use is restricted with separate security levels set for enabling patient data entry, general access to data, changing or acceptance of examination results, reporting results and authorising reports. Other software applications are password protected and safeguarded against unauthorised access, tampering, loss of information and breach of confidentiality. Patient confidentiality is maintained [DOC2051].

Databases and information systems are operated in an environment that complies with supplier specification and maintained to ensure data access and integrity. All non-conformances or failures associated with data systems and software (affecting laboratory activities and impacting patient care) are recorded on Q-Pulse and/or Ulysses and investigated appropriately.

* + 1. **Downtime Plans**

The Laboratories have contingency plans to maintain operations/services in the event of failure or prolonged downtimes of information management systems [DOC6001, DOC2809, DOC5433]. Automated reporting is not applicable.

* + 1. **Offsite Management**

Information system management is supplied by the MFT IT Department. The NW GLH is also supported by an IT Team within NW GLH Manchester. As an NHS organisation, MFT adheres to industry standards, cyber security best practice and continuous improvement.

In cases where laboratory information is stored off-site (e.g., within a Cloud environment), the supplier is assessed prior to implementation and where appropriate, a data protection impact assessment (DPIA) is completed. This informs how the provider will ensure that the data remains safe from tampering or loss, secure, free from unauthorised access, is stored appropriately and available for retrieval.

* 1. **Complaints**

The Laboratories have a process for receiving, handling, investigating, and recording complaints [DOC1187]. A description of the process is publicly available on the MFT and NW GLH websites. Informal complaints made directly to a laboratory are recorded on Q-Pulse. Formal complaints are made through the Trust Patient Advice and Liaison Service (PALS). Complaints are acknowledged with the complainant, fully investigated, and feedback on the outcome is given, if applicable. Complaints can be translated into corrective actions or quality improvements and form the focus of laboratory objectives. Complaints are discussed in Quality Management meetings and Divisional Quality & Safety Committee meetings. Complaints are summarised in the Annual Management Review.

* 1. **Continuity and Emergency Preparedness Planning**

There are Trust Emergency Preparedness, Resilience and Response (EPRR) policies, plans for major/critical incidents, and business continuity plans ([here](https://intranet.mft.nhs.uk/content/corporate-services/eprr-6/emergency-planning_1/emergency-plans-eprr-policies-sops-and-procedures)). There is mandatory training on Major Incidents and optional training on Business Continuity Management. The Trust EPRR Team plan and support EPRR exercises and testing ([here](https://intranet.mft.nhs.uk/content/corporate-services/eprr-6/eprr-exercise-testing)).

There are Trust and local site level business continuity plans for emergency situations or conditions affecting laboratory activities defined in:

* DOC6001 Trust Business Continuity Plans
* DOC2809 NW GLH Manchester - Business Continuity Plan
* DOC5433 Willink Biochemical Genetics Business Contingency Plan
* DOC6349 Christie Oncology Cytogenetics Business Continuity Plan.

Business continuity plans, activated as part of mitigation to an identified risk impacting patient service/care, will be communicated to users as appropriate (e.g., temporarily redirecting testing to another GLH/centre).

Local plans are tested, and response capability exercised where/when practicable; exercising plans are scheduled and recorded.

1. **Management System Requirements**
   1. **General Requirements**

The Laboratories maintain a robust quality management system, as evidenced by UKAS accreditation to ISO 15189:2012 and transition to ISO 15189:2022, which fulfils the requirement of ISO 15190:2022. This document informs the management system, fulfils the requirements of ISO 15189, clauses 4-7 [DOC1191, sections 4-7] and ISO 15189, clauses 8.2-8.9 [DOC1191, sections 8.2-8.9]. The Laboratories do not use ISO 9001 certification to demonstrate compliance of the management system.

The quality policy [DOC1018], quality manual [DOC1191], quality objectives [DOC1343], annual management review [DOC1020] and other laboratory quality management policies are available on Q-Pulse to all staff (ISO 8.1.1). Following review or update, these documents are distributed to all staff to read, requiring an acknowledgment to be entered by individual staff on Q-Pulse, ensuring an awareness of relevant objectives and policies (ISO 8.1.3a). Staff are required to follow all relevant laboratory policies and procedures and conform to the management system requirements.

Meeting agendas promote management system awareness and improved performance. ‘Quality’ is a standard meeting agenda item across all meetings with the aim to engage staff at all levels with the management system. Quality management is included in induction training.

Important communications from the Quality Team, Quality & Safety Committee, and Joint Laboratory meetings are shared regularly via email and/or displayed on communication boards and inform effectiveness of the management system and/or consequence of non-conformances/errors to patient care (ISO 8.1.3b,c).

The Quality Management Team meets to discuss the strategy of the quality management system and to monitor, evaluate and improve the effectiveness of the quality management system.

* 1. **Management System Documentation**
     1. **General**

The components and relationships within the quality management system are described in section 4-8 of this Quality Manual. Laboratory management system documentation, including objectives and policies, and the quality manual are distributed and acknowledge by all staff at all levels via Q-Pulse.

* + 1. **Competence & Quality**

The quality policy [DOC1018], this document [DOC1191], laboratory objectives [DOC1343], and the annual management review [DOC1020] address competence, quality, and operation of laboratory activities.

* + 1. **Evidence of Commitment**

Laboratory management is committed to the development and implementation of the (quality) management system and its continual improvement as evidenced by: laboratory communication and communication processes (including laboratory meetings), the quality policy, quality objectives developed from strategy and operational management meetings, staff responsibilities, the appointment of a quality manager and quality team, annual management reviews, audit schedule, monitoring of key performance indicators, non-conformance and quality improvement register, staff competency, and management of resources necessary for pre-examination, examination and post-examination activities.

* + 1. **Documentation**

Documentation and records relating to laboratory processes and management system are managed and available to all staff via Q-Pulse. The main quality management system documentation consists of the following:

* Quality Policy [DOC1018]
* Quality objectives agreed and documented [DOC1343]
* A quality manual [DOC1191] which references other documentation on Q-Pulse
* A copy of ISO 15189:2022, accessible in hard copy
* Other laboratory policies, procedures, documents, and forms, controlled and reviewed on Q-Pulse
  + 1. **Personnel Access**

All laboratory documentation is managed, controlled, and held within Q-Pulse; all staff are provided with a login and access to the software and read access (as a minimum) to stored documentation. The ISO 15189:2022 standard hard copy is available to all staff as required.

* 1. **Control of Management System Documents**

Laboratory documents (including policies and procedure, validation/verification records, COSHH records, manuals, forms, and other relevant external documents) are controlled using Q-Pulse [DOC845, DOC842, DOC843, DOC2739, DOC2889 and DOC846]. Each document is uniquely identified by a document number [DOC845]. New documents on Q-Pulse are approved for adequacy by authorised personnel prior to use [MP 000 135]. Similarly, existing documents on Q-Pulse are regularly reviewed, updated, and approved for adequacy by authorised personnel prior to use [MP 000 135]. Document approval is always by a person who has the expertise and competence to determine adequacy. Approval includes a final document review by a designated staff member (document controller) [DOC1196]. They have specific areas of responsibility and report formally via Quality Management team meetings. Version control is in place with only documents used from an active register. Use of the document module in Q-Pulse is included in induction training for all staff and recorded [DOC841]. Document changes are recorded in the change details box of the Q-Pulse record. All staff have a unique log in for read-only Q-Pulse access and specified permissions to ensure that documents are protected from unauthorised access, changes, and deletion/removal. Obsolete documents are retained in a separate register of Q-Pulse to prevent unintended use but still allow for access (e.g., examination process records are available to reconstruct the process of any examination). Documents are organised in Q-Pulse depending on the department and nature of the document. Some historical documents (validations/verifications, instructions, and manuals) are kept as paper copies.

Equipment maintenance and calibration records (and some manuals) care controlled using the Q-Pulse Assets module. Each asset is uniquely identified by a reference number. These records are managed by appropriate staff members with specified permissions. Appropriate staff have read-only access. Willink Laboratory standards and reference data is stored in Unity.

Standard operating procedures should be strictly followed and failure to do so may be regarded as misconduct and could incur disciplinary action. Staff have a duty to raise any discordance between a procedure and its documentation via the Q-Pulse quality management system (by raising a change request) and document owners have a duty to complete any critical document changes promptly.

Trust documents can be accessed by all staff through the intranet in read-only format ([here](https://intranet.mft.nhs.uk/documents/policies/554)). A separate document control process exists for documents relating to MFT policies (Trust policy - Document Control Policy). The Laboratories do not retain documents on the Trust intranet system.

* 1. **Control of Records**

The Laboratories have procedures to meet the requirements for controlling process records and quality records [DOC1279]. Appropriate and legible records relating to relevant laboratory activities are created as required. DOC1279 details the management of all records, their storage, security, archive, retrieval, retention time, and disposal. DOC846 further details the control of external records. The Laboratories comply with current legislation, regulations and guidelines determining the timescales for storage of such records (NHS & RCPath). There are procedures for the amendment of records [DOC1279] and laboratory reports [DOC2048].

* 1. **Actions to Address Risks and Opportunities for Improvement**
     1. **Identification of Risks and Opportunities for improvement**

The Laboratories identify risks and opportunities for improvement associated with laboratory activities to mitigate risks to patient care, improve services and fulfil laboratory objectives. These can be identified through various routes including incident reporting [DOC1006]; risk assessments [DOC5705]; user complaints, feedback, and surveys [DOC1187]; staff suggestions [DOC1187]; EQA performance review [DOC1564]; external assessment and via discussion at various laboratory meetings. See also 5.6 and 8.6.

The Laboratories aim to reduce risks to acceptable levels by preventing or reducing the possibility of undesired impacts and potential failures which could impact on the ability of the Laboratories to provide accurate, timely results to patients. Risks with the greatest potential for harm are prioritised and actioned immediately if possible. Risks can be raised (and managed) via the Trust risk register and actions to mitigate risks can also be raised as quality improvement projects.

* + 1. **Acting on Risks and Opportunities for Improvement**

Appropriate control measures are put in place to reduce or prevent undesired impacts and potential failures that have been identified. Improvements are achieved where actions are taken to reduce or eliminate a risk or by acting on a new opportunity (e.g., technology advance/transfer); actions are proportional to the benefit and the impact on the patient or activity. Audit, performance monitoring (internal and external), trend analysis and management review provide assurance that the management system continues to achieve its intended results and that implemented actions and changes are effective.

Formal risks are raised, approved, controlled, actioned, and monitored using Trust procedures and the web-based risk register (Ulysses; see also section 5.6). Risk controls are evaluated (e.g., alternative measures, contingency plans), and actions are put into effect (e.g., finance requests for staff/equipment, loan equipment, recruitment, test/equipment validation/verification). Risks are graded based on severity and likelihood, with higher level risks prioritised and evaluated at Hospital/Group level [DOC5705]. Other identified risks and opportunities can be recorded on Q-Pulse as a quality improvement project (QIP) [DOC6029] and can inform quality objectives.

* 1. **Improvement**
     1. **Continual Improvement**

Quality improvement is essential to ensure that the Laboratories continue to deliver a high-quality, robust, and timely service to patients. Improvement activities are prioritised based on service needs, risk, and patient care outcome. The Laboratories identify and select opportunities for improvement from many sources including risks assessments; reviews of policies, procedures, and workflows; strategy, objective setting, and operational management meetings; discussion at team and quality meetings; incident reporting; internal or external evaluations (audits); external quality assessment (EQA) results; data analysis including that of internal quality control; feedback and suggestions from staff or service users; and management reviews. Quality improvement can be proactive (e.g., new ideas about different ways of working, achieving increased efficiency) or reactive (e.g., errors and incidents).

Potential improvements are raised on Q-Pulse as staff suggestions or as quality improvement plans (QIPS). The Q-Pulse framework for quality improvement, change management and project management [DOC6029] was developed to allow for the raising of quality improvement ideas, their acceptance (or rejection), progression and completion. For each QIP, roles and responsibilities, business/finance, project management, validation/verification, implementation, and UKAS requirements are considered and documented [DOC6030, DOC6031, DOC6032]. Improvement actions are developed and monitored in various team meetings (e.g., operational management, development team and quality team meetings). They are communicated to staff via various meetings, laboratory objectives [DOC1343] and the annual review [DOC1020]. The effectiveness of quality improvements is evaluated (e.g., internal audit following implementation, changes to KPIs for turnaround times, user surveys).

* + 1. **Laboratory Patients, User, and Personnel Feedback**

The processes for patient, user and personnel feedback are described in DOC1187. All feedback is recorded, assessed, and acted upon where appropriate. Feedback can be translated into corrective or preventive actions and form the focus of objective setting and planning. Feedback is compiled and presented in the Annual Management Review.

Patient feedback is received via service users or as formal complaints via Trust PALS. The laboratories receive user feedback as compliments, suggestions, comments, concerns and complaints via telephone, email, MDT meetings and via user satisfaction surveys. User surveys can provide an opportunity to assess the clinical relevance of investigations performed within the Laboratories and the suitability of interpretive reports in conjunction with users. When possible and appropriate, feedback is acknowledged, and any actions communicated. The results of user satisfaction surveys are recorded on Q-Pulse within the audit module. All other feedback is recorded in the non-conformance module of Q-Pulse. Feedback

Staff are encouraged to make suggestions for the improvement of any aspect of the laboratory service via line managers, Q-Pulse, staff suggestions boxes/whiteboards and a staff forum. Decisions and outcomes from the staff suggestions are fed back to staff at relevant meetings or via email.

* 1. **Nonconformities and Corrective Actions**

The management of nonconformities (see section 7.5) follows a defined process [DOC1006]:

* Immediate response - remedial action(s) taken in response to the incident, to control and correct the nonconformity and ensure patient safety.
* Escalation and halting work – as required, escalation to the Team/Programme Lead, to consider appropriate actions (e.g., isolating/withholding results).
* Investigation – to determine the cause(s) and contributing factors, establish the significance of the non-conformance, to establish the risk of recurrence, and to determine the extent of risk to work, risk to other patients, and impact on the patients involved.
* Corrective action – long-term action to address any potential consequences, mitigate the nonconformance and eliminate/reduce the risk of recurrence.
* Resumption of work – as required, resumption of work, reporting of results (or amended results).

All nonconformances are recorded in Q-Pulse. Appropriately trained staff review non-conformance actions for their effectiveness and approve non-conformance records. Trend analysis is performed at regular intervals to monitor underlying themes and evaluate effectiveness of corrective actions. The investigation of incidents and non-conformances may uncover other potential risks or highlight areas for improvement. As part of continual improvement, all nonconformities are reviewed by an Incident Lead 3-6 months following reporting to ensure that all corrective actions have been completed and to check for further instances of the nonconformity for error trends. Any trends and concerns are raised at Quality Management Team meetings.

* 1. **Evaluations**
     1. **General**

The Laboratories conduct various evaluations of laboratory activities and management systems at planned intervals to ensure that there is continued compliance to the ISO 15189:2022 standards and to ensure that the needs of patients and users are met. Evaluations include those for test volumes, test turnaround times and backlogs, audits, non-conformities and incidents, document control, risks, feedback/complaints, and EQA. Certain sets of these are discussed at various meetings including team meetings, quality management meetings, operational management meetings and NHSE assurance meetings.

The Laboratories (but not yet the Christie laboratory) are accredited by external assessment and are currently fully UKAS accredited under reference 9865 [DOC4165, DOC2252, DOC4157, DOC5323, DOC6041]. External accreditation assessment is recorded as an audit on Q-Pulse and all assessment findings recorded as non-conformances.

* + 1. **Quality Indicators**

Laboratory key quality indicators are recorded and monitored [DOC1017] to evaluate performance throughout critical aspects of pre-examination, examination, post-examination, and quality management systems (e.g., mandatory training, appraisal, turnaround times, document reviews, EQA performance). Indicators are presented and reviewed at monthly quality meetings and form part of the annual management review. The policy is regularly reviewed to ensure the continued appropriateness of quality indicators.

In addition, the NW GLH has a contract with NHS England to supply the genomics service. Contract monitoring includes the requirement to provide patient level contract monitoring (PLCM) data to assess laboratory activity and turnaround times ([here](https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/)) as well as information on backlogs, UKAS accreditation, EQA, and patient safety incidents.

* + 1. **Internal Audits**

The Laboratories plan and conduct an annual schedule of audits to ensure continued compliance with the ISO 15189:2022 standard and other guidelines, that the requirements of the laboratory policies and procedures are met, and that the management systems are implemented and maintained effectively [DOC1288]. Other internal audits are agreed on an ad hoc basis and may arise from incidents and non-conformances, identified risks, complaints, findings from external reviews or previous audits, and from changes to laboratory activities. Those ad hoc audits with the greatest potential for risk to patients (e.g., from incidents and risks) are scheduled immediately and given the greatest priority over other unplanned incidents, which are given priority over those audits on the annual schedule.

Audits are conducted against agreed criteria (as check lists) and scope (usually relevant ISO 15189:2022 standard clauses) and recorded in the Q-Pulse audit module. Examination, Vertical and Horizontal audits are conducted following laboratory policy and procedures [DOC1288, DOC1509, MP000 043]. Audit findings are recorded as nonconformities on Q-Pulse. Auditors and Audit Officers are appropriately trained and authorised to perform and manage internal audit respectively [QF 000 002]. Audit Officers ensure that appropriate actions are completed and that results of audits are reported to relevant personnel. Where possible auditors are independent from the activity being audited ensuring objectivity and impartiality. The results of internal audit are reviewed in monthly Quality Management meetings and in the annual management review.

* 1. **Management Reviews**

Quality Management and Senior Management representatives conduct an annual management review (AMR) and produce a report [DOC1020]. The report considers the items detailed in the agenda template [DOC5309] relating to the management requirements specified in the ISOS 15189:2022 standard. The draft report is shared with key staff for their consideration to inform the output from the review, which is then added to the report. The final AMR report [DOC1020] is available to all members of staff on Q-Pulse.

Input into the AMR report includes:

* Reports from key laboratory sections with reference to major changes in organisation and management, resources (including staffing), volume and type of laboratory activities, test turnaround times, and a forward view.
* Review of annual objectives.
* Report from the Quality Team including reviews of laboratory evaluations and monitoring against key performance indicators for document control, internal audits, non-conformities (including Trust incidents), review by external organisations (UKAS)
* The review and status of actions from the previous review.
* Assessment of user feedback/complaints and staff suggestions.
* Review of external quality assessment GenQA[[1]](#footnote-1), UKNEQAS[[2]](#footnote-2), EMQN[[3]](#footnote-3), ERNDIM[[4]](#footnote-4) and CDC[[5]](#footnote-5).
* Review of risk management and improvement actions.
* Performance of external suppliers.
* Review of training and competency.

The AMR report also informs the output of the review and includes:

* Recommendations for improvement as new objectives.
* Review of the effectiveness of the management system.
* Actions arising from the review.

1. Genomics Quality Assessment (part of UK NEQAS) [↑](#footnote-ref-1)
2. United Kingdom National External Quality Assessment Schemes: (a) Molecular Genetics, (b) Leucocyte Immunophenotyping, (c) Blood Coagulation, (d) Histocompatability & Immunogenetics and (e) Haematology [↑](#footnote-ref-2)
3. European Molecular Genetics Quality Network [↑](#footnote-ref-3)
4. European Research Network for evaluation and improvement of screening, Diagnosis, and treatment of Inherited disorders of Metabolism [↑](#footnote-ref-4)
5. Centres for Disease Control [↑](#footnote-ref-5)