NHS
North West
NHS Genomic Laboratory Hub

Joint Laboratory Quality Manual

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North West Genomic Laboratory Hub (Liverpool)

Introduction and Scope

This document describes the laboratory, its services and context within Liverpool Women's NHS Foundation Trust and includes details of the management structure, a directory of laboratory documentation and the quality management system in relation to the eight sections of the CPA (UK) Ltd 'Standards for the Medical Laboratory'.

Contents

1 General Information

1.1 Departmental Information

The genetics laboratory based at Liverpool Women's NHS foundation Trust (LWH) forms part of the North West Genomics Laboratory Hub, managed by Manchester Centre for Genomic Medicine (MCGM), based at Manchester University NHS Foundation Trust (MFT). This allows the collaboration and combining of specialist knowledge from experts across the North West, with laboratories from The Christie NHS Foundation Trust, Liverpool Clinical Laboratories and Lancashire Teaching Hospital NHS Foundation Trust also joining the hub as local genomics hubs.

This change has been brought about due to reconfiguration of genetics laboratories by NHS England in order to create a national NHS genomic medicine service. Although this process was commenced some time ago, the laboratory based at Liverpool Women's NHS Foundation Trust officially came under the management of MFT on 1st August 2019.

A process of change has since been implemented and the two laboratories are currently working to align. The name of the genetics laboratory based at LWH has been changed from The Cheshire and Merseyside Regional Genetics Laboratory to North West Genomics Laboratory Hub – Liverpool Site (NWGLH – Liverpool Site) and the legal entity (legal entity: 4.1.1.2) is now Manchester Foundation Trust (MFT). UKAS have been informed of this change and work is ongoing to submit a change of legal entity.

The postal address is:- **North West Genomics Laboratory Hub – Liverpool Site**
Liverpool Women's NHS Foundation Trust
Crown St
Liverpool L8 7SS

Information on the services provided and contact telephone numbers is available and on the hospital website. *(www.liverpoolwomens.nhs.uk)*
The North West Genomics Laboratory Hub – Liverpool Site is comprised of a combined Cytogenetics and Molecular Genetics Laboratory with a single budget and management structure. The laboratory is divided into 4 streams: Germline, Acquired; Technical and Development. The overall structure can be seen in section 3

The laboratory offers a comprehensive service for the diagnosis of constitutional genetic disorders, including a wide range of inherited single gene genetic disorders, and acquired disorders in a limited range of cancers using whole genome analysis or targeted analysis.

The laboratory offers cytogenetic testing via karyotyping; an extensive FISH testing service; and testing for an extensive range of molecular genetic disorders including core for the Cheshire and Merseyside population, Isle of Man and specialist Fetal Medicine services for North Wales and other areas in the Northwest Region. Some tests are now also offered across the whole North West GLH area and, through a deduplication process, certain tests have been exchanged with the Manchester Site.

The laboratory maintains a fibroblast cell bank for tissue from children with inherited metabolic disorders and a DNA banking service for patients where no testing is currently available.

The laboratory is a designated specialist Cytogenetics testing centre for the Haematological Oncology Service (NICE IOG).

Specialised services are offered as part of the NHS Genomic Medicine Service on a national basis through the National Genomic Test Directory whereby Genetics Laboratory Hubs in England are responsible for specific specialist test groups

(https://www.england.nhs.uk/genomics/). The test directory originated from an NHS Directory of Genetic Disorders/Genes previously established and validated via gene dossiers by the UK Genetic Testing Network (UKGTN)

1.2 The Quality Manual

This Quality Manual describes the Quality Management System of the **North West Genomics Laboratory Hub – Liverpool Site**. Throughout the text there are references to ISO 15189:2012 Standards (in brackets) and to relevant information and documents written in fulfillment of these standards.

This Quality Manual fulfills two functions. It describes the Quality Management System for the benefit of the laboratory's own management and staff, and it provides information for users and for inspection/accreditation bodies.

This Quality Manual can be regarded as the index volume to separate volumes of management, laboratory, clinical and quality procedures. The sections of the Quality Manual are arranged so that they equate with the ISO 15189:2012 Standards (see table below). Under the title of each standard there is a brief description of the way in which the **Genetics Laboratory** seeks to comply with the particular standard and references are given to appropriate documents.

The various clauses of the standard should be seen to relate to each other

Section in the Quality Manual	Section of ISO 15189 Standard
4	**Management Requirements**
4.1	A Organisation and Management Responsibility
4.2	Quality Management System
4.3	Document Control
4.4	Service Agreements
4.5	Examination by referral laboratories
4.6	External services and suppliers
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4.11	Preventive action
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2 Quality Policy

The NWGLH – Liverpool Site provides a wide range of genetic testing services to the Northwest region, including the Isle of Man and North Wales. The laboratory also receives both national and international referrals for a number of specialist services.

The laboratory is committed to providing a high-quality service that considers and aims to meet the needs and requirements of its users.

To ensure that the needs and requirements of users are met the laboratories shall:

- Operate a quality management system, which integrates the organisation, procedures, processes and resources of the laboratory and which facilitates the setting of quality objectives aimed at achieving continual improvement of laboratory services to ensure user satisfaction.
- Ensure that all laboratory personnel are familiar with this quality policy and all procedures relevant to their employment and duties.
- Commit to the health, safety and welfare of all laboratory staff and visitors.
- Seek to ensure that all staff and visitors to the department are treated with respect and due consideration.
- Show commitment to professional best practice, good conduct and adherence to relevant statutes and guidelines.
- Comply with relevant environmental legislation and seek to minimise any potential or actual detrimental impact its activities have on the environment.

The laboratory will comply with standards set by UKAS (ISO 15189:2012) and are committed to:

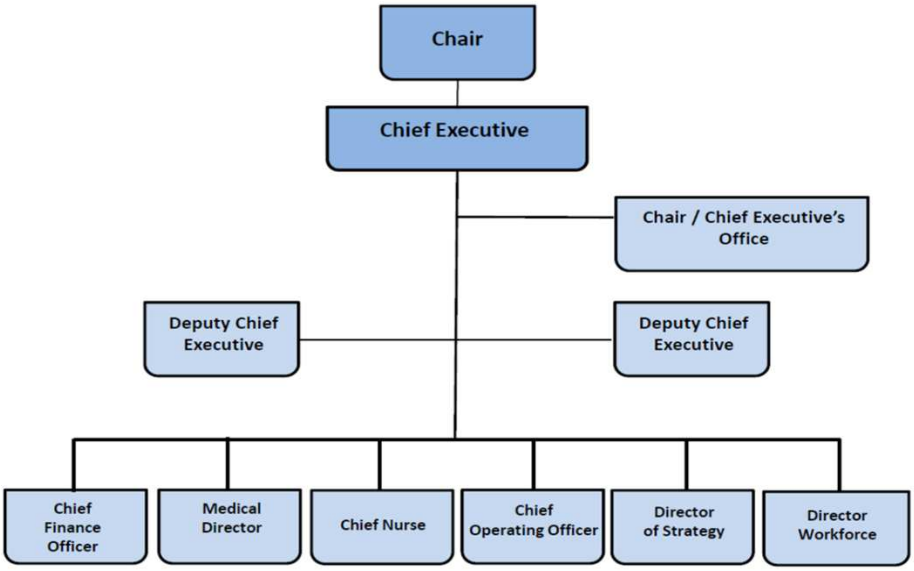
- The recruitment, induction training and continual development of staff at all levels as necessary to provide a full and effective service to their users.
- The proper procurement and management of fiscal and material resources necessary for the provision of their services
- Ensuring the proper collection, transport, storage and handling of all samples to allow the correct performance of all their laboratory examinations.
- The use of examination procedures that will ensure the highest achievable quality of all tests performed.
- Reporting results of examinations in ways which are timely, accurate, confidential and clinically useful.
- The use of internal audit, external quality assessment and the evaluation of user satisfaction to achieve continual quality improvement.

Agreed and Signed:  (Head of Liverpool Service NWGLH)

Date: 10/01/2020

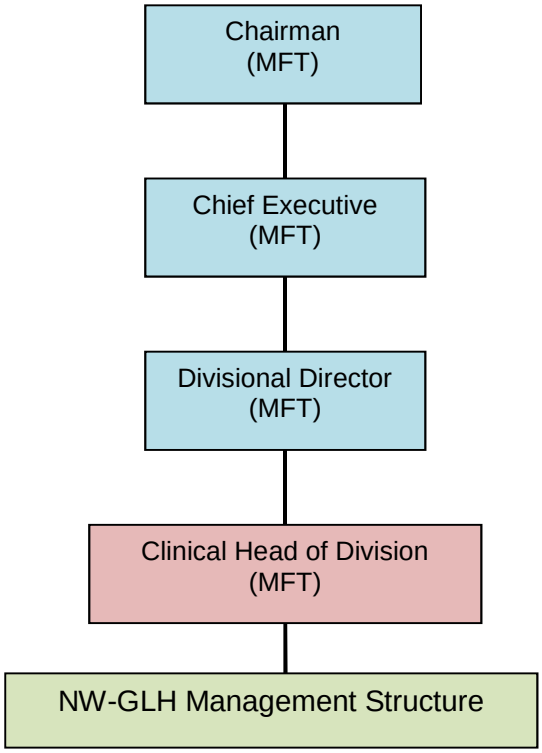
3 Organisation, responsibilities and authorities

3.1 The Host Organisation (MFT)



3.2 Relationship to the Host Organisation

The NW-GLH Liverpool Site forms part of the NW-GLH, which has a defined management structure that feeds into the Host Organisation management as shown below:



3.3 Organisation and Responsibilities within the North West Genomics Laboratory Hub – Liverpool Site. (Laboratory Director – Organisational Responsibilities 4.1.1.4)

The Scientific Operational Director for the North West Genomics Laboratory Hub is Andrew Wallace (Interim Scientific Director) who is currently ultimately responsible for the following issues where relevant:

- Professional
- Scientific
- Consultative/advisory
- Organisational
- Administrative
- Educational

However, on a day-to-day basis, at the Liverpool Site, the requirements of 4.1.1.4 are assumed by the Head of Laboratory service; the responsibilities are described within the job description and Quality Team Roles policy (GEN 804), which also details the delegation of these responsibilities, as per the organisational plans below.

Organisation and Service Responsibilities

The NWGLH – Liverpool Site Laboratory is divided into 4 streams:

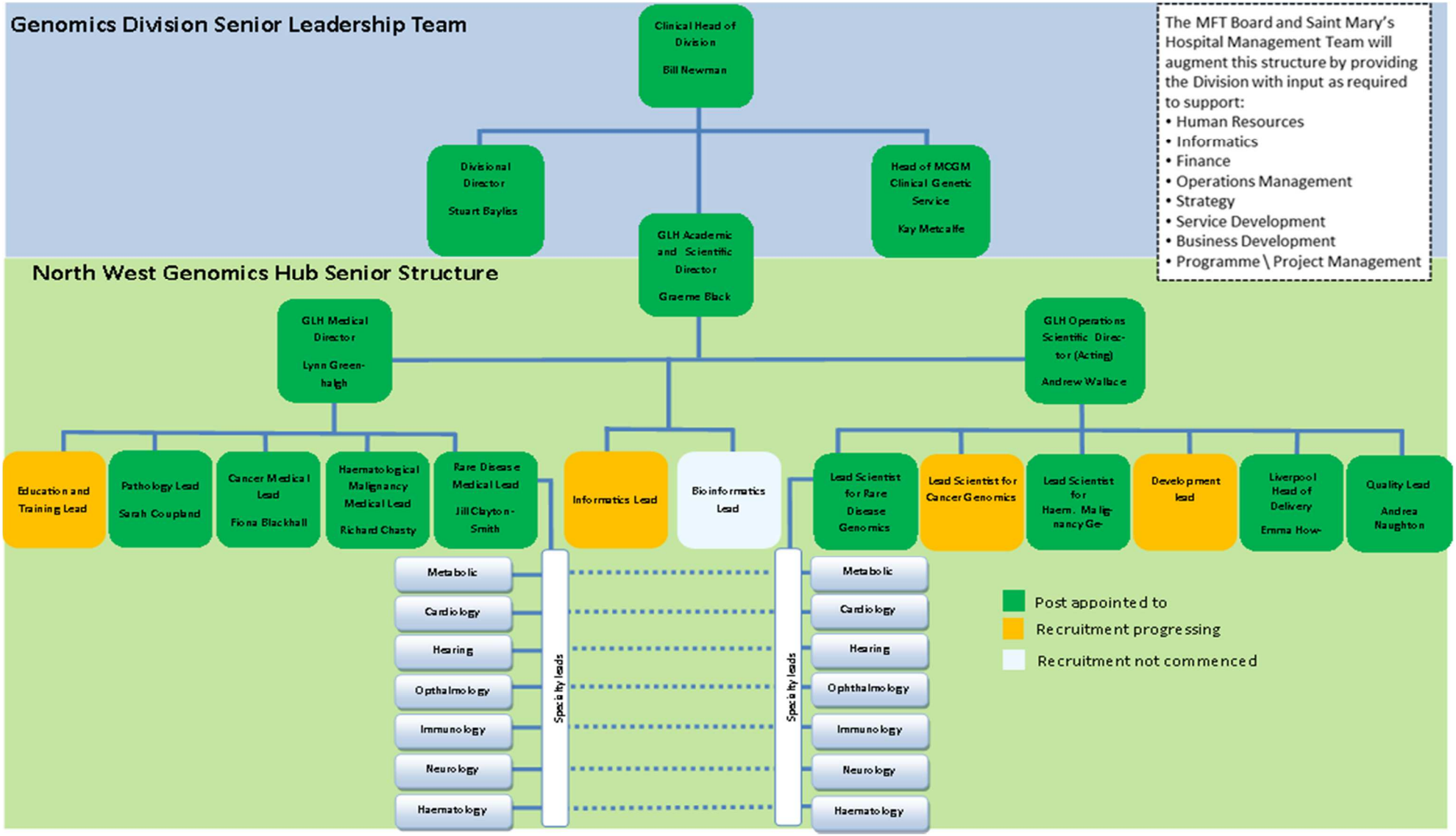
- Technical
- Germline Genetics
- Acquired Genetics
- Development

Germline and Acquired Genetics Teams are each headed by a Senior Principal Clinical Scientist who reports to the Head of the service. Cross professional cover is provided by these key members of staff.
Germline and Acquired Genetics Teams are then broken down into functional sections which, along with the technical programme, are all headed by Principal Clinical Scientists.

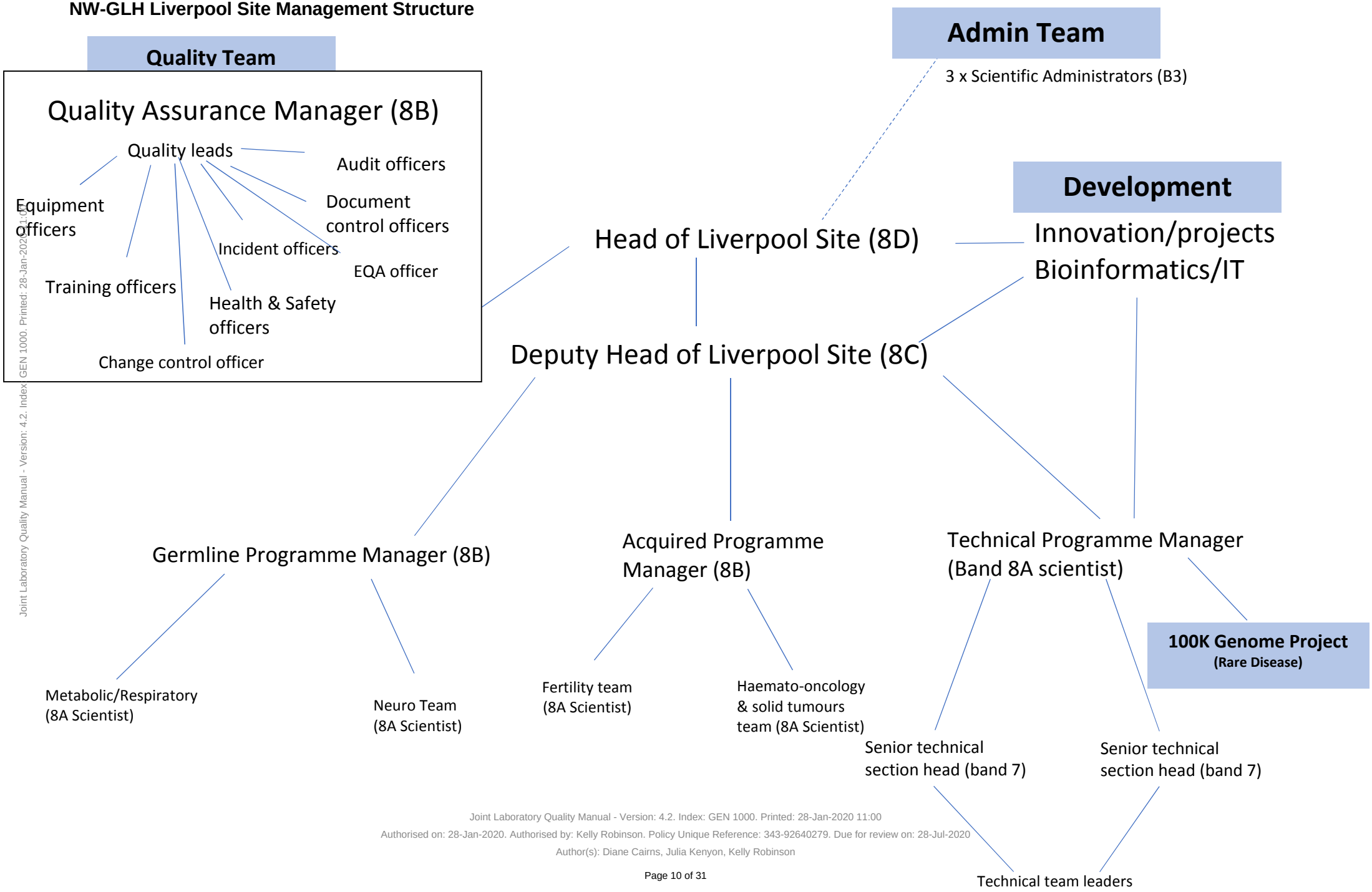
The Genetics Laboratory has a strong management structure which feeds into the Head of service and is led by the Scientific Operational Director who provides general management and strategic support. The administration and clerical function sits within this management unit, as does Quality and Information Technology Management.

The Quality Manager, based on the Manchester site of the NWGLH, is responsible for overseeing the design, implementation, development and co-ordination of quality processes and quality aspects of procurement projects within Genetics, the day-to-day running of the quality management system on the Liverpool Site is delegated to the Quality Leads. The Quality Manager oversees the Quality Management system and integration of this system in to the trust governance and risk management systems. The objective being, that the Genetics Laboratory become progressively more effective in quality terms and meets both regulatory and accreditation requirements.
The quality management system is maintained through the quality team structure.

NW GLH Management Structure



NW-GLH Liverpool Site Management Structure



Scientific Teams

Metabolic/Respiratory	Neurology	Fertility	Oncology	100K Genome Project (Rare Disease)
Clinical Scientist (B7) [maternity]	Clinical Scientist (B7)	Clinical Scientist (B7)	Clinical Scientist (B7)	Clinical Scientist (B7)
Clinical Scientist (B7) [maternity]	Clinical Scientist (B7)	Clinical Scientist (B7)	Clinical Scientist (B7)	Clinical Scientist (B8a) 0.6
Clinical Scientist (B7) WTE 0.8	Clinical Scientist (B7)	Clinical Scientist (B8a) WTE 0.5	Clinical Scientist (B7)	
Clinical Scientist (B7) WTE 0.6	Clinical Scientist (B8a) WTE 0.5	Clinical Scientist (B8a) WTE 0.5	Clinical Scientist (B7) WTE 0.6	
Clinical Scientist (B7) WTE 0.6			Clinical Scientist (B7) WTE 0.65	
Clinical Scientist (B8a) WTE 0.5			Clinical Scientist (B7) WTE 0.8	
			Clinical Scientist (B7) WTE 0.75	
			Clinical Scientist (B8a) WTE 0.5	
			Clinical Scientist (B8d) When required	

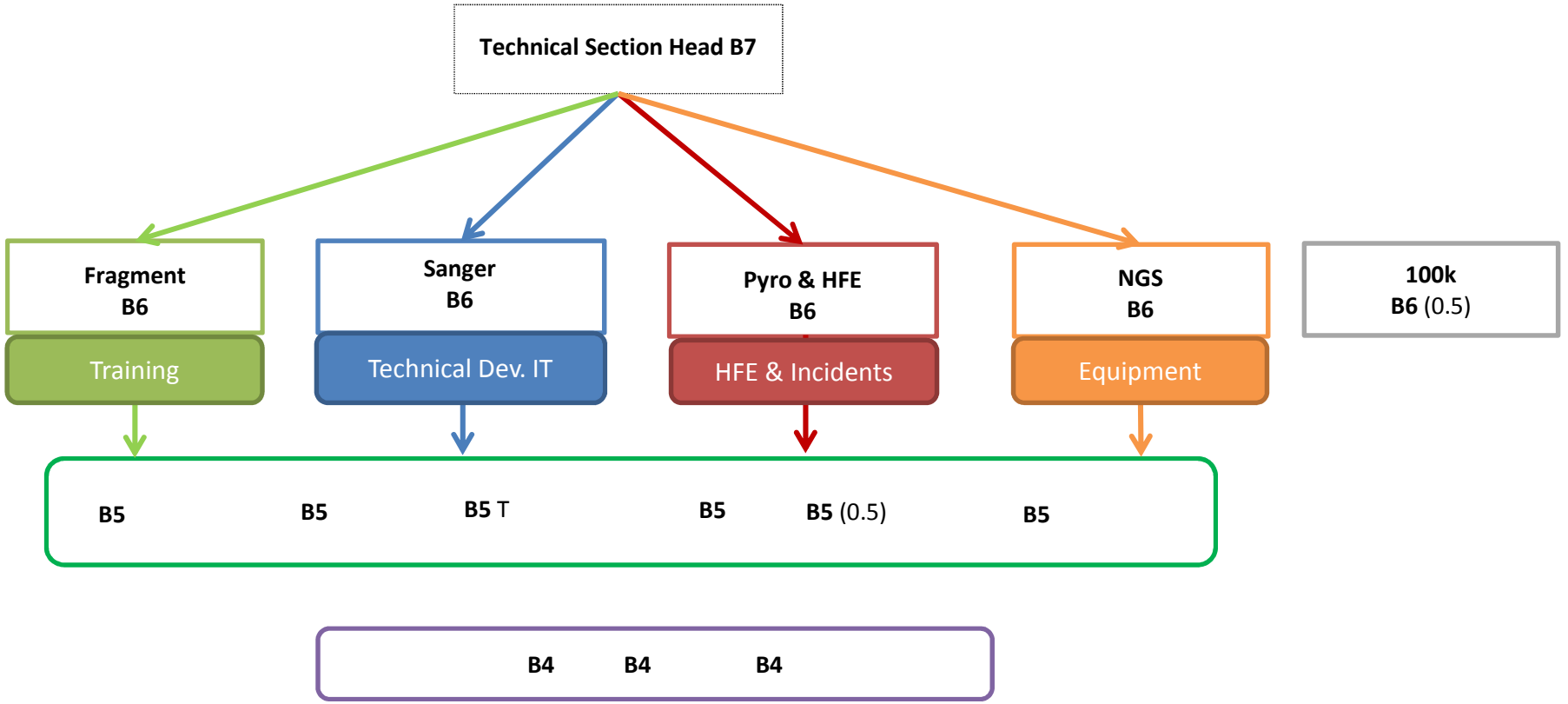
Bank Staff

Clinical Scientist (B7)

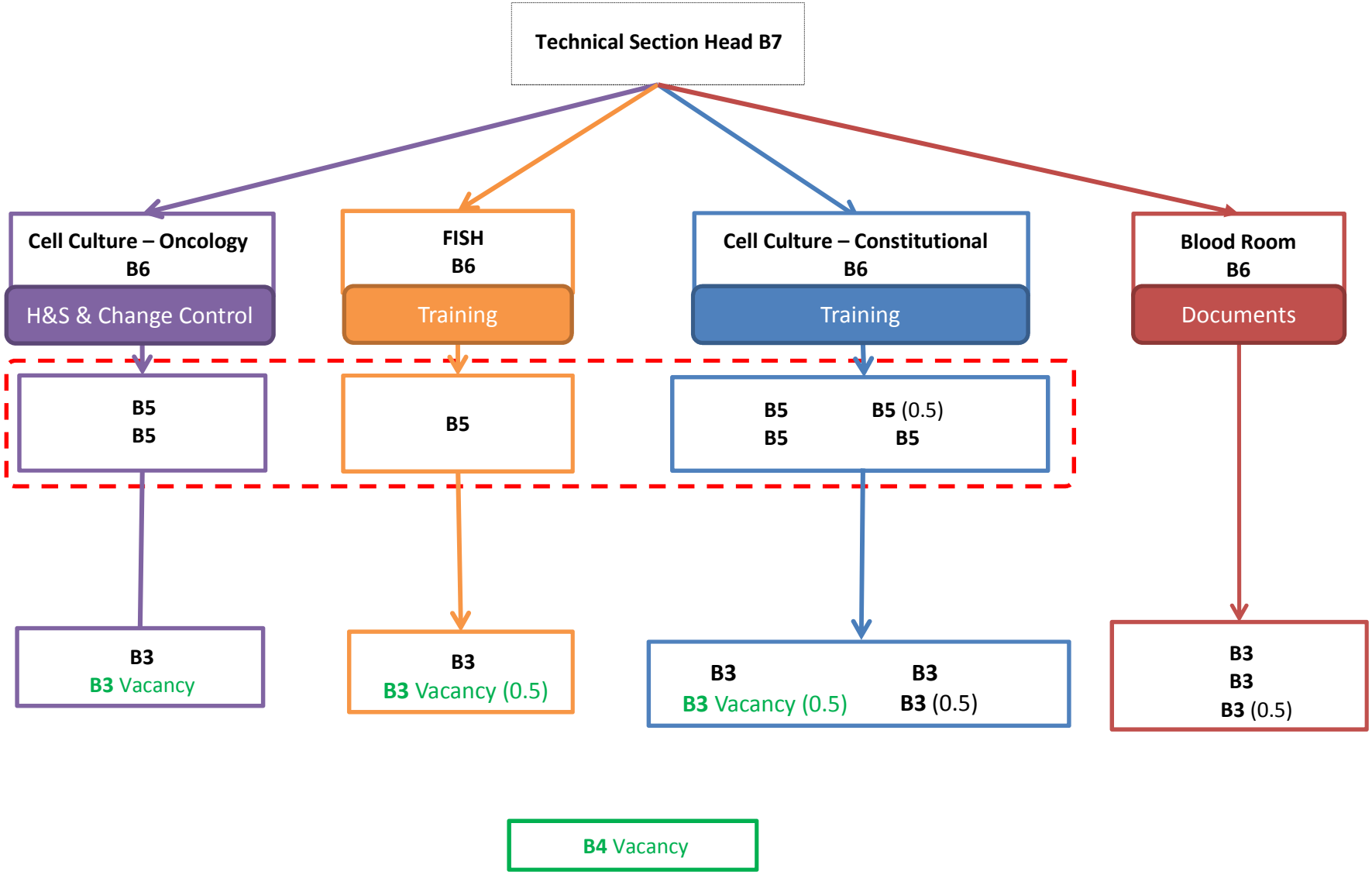
Clinical Scientist (B7)

Route 2 Trainees

Currently there are 3 Clinical Scientist Route 2 Trainees in rotation



Please note that this does not reflect line managerial duties


Technical Section Head B7
Cell Culture – Oncology
B6
H&S & Change Control
FISH
B6
Training
Cell Culture – Constitutional
B6
Training
Blood Room
B6
Documents
B5
B5
B5
B5
B5 (0.5)
B5
B3
B3 Vacancy
B3
B3 Vacancy (0.5)
B3
B3 Vacancy (0.5)
B3
B3 (0.5)
B3
B3
B3 (0.5)
B4 Vacancy

3.4 Departmental Committees and meetings (4.1.2.6)

This standard is fulfilled by procedure GEN 618: Laboratory Management Procedure

The **Strategy Team** meets weekly. Its membership is as follows:

Strategic Director
Clinical Lead
Director of GDL
Directorate Manager
University Lead
100 000 Genome Project lead
The team is joined once a month by the SMH Divisional Director

(Please note: meetings occur at MFT and all minutes relating to this meeting are held there)

Senior Operational Meeting – Held monthly at MFT to discuss boith sites operational delivery. Attended bu Head of Liverpool Service and Technical Programme Manager.

Mobilisation Operational Delivery Group – Held monthly at MFT to support merge of labs. Attended by Head of Liverpool Service.

Trust Health + Safety committee – Ed McHale represents Genetics at the quarterly Trust meeting. This is fed back to NW-GLH Liverpool site through the Clinical Effectiveness Meeting and Quality Meeting.

Clinical Effectiveness Meeting – Departmental monthly meeting including representatives from Laboratory and Clinical Genetics. Clinical governance, information governance and high level incidents are discussed at this meeting. ((Please note: meetings occur at MFT; all minutes relating to this meeting are held there but are circulated to the Quality Leads at the Liverpool Site)

NWGLH Rare Disease Group – Chaired by Simon Ramsden and attended by Liverpool Rare Disease programme manager. Meets monthly.

Quality Management Group -meets monthly and the membership is as follows (A representative will be present or feedback provided if a member cannot attend):
Quality Manager
Head of Genetics laboratories
Deputy Head of Genetics
Germline Programme Manager/ Acquired Programme Manager (alternating)
Health & Safety Lead
Quality Leads
Fire Officer (information to be provided via H&S lead if not in attendance)
Audit Officer
Document Control Officer
Change Control Officer
EQA Officer
Incident Officer
Development Team representative

This meeting incorporates the previous Health & Safety Group.

All Quality team roles and responsibilities are encompassed within document GEN 804.

Laboratory Senior Management Team – meets monthly. Core membership is as follows:
Head of Genetics laboratories
Deputy Head of Genetics
Germline Programme Manager
Acquired Programme Manager
Technical Programme Manager

Training Committee- meets monthly. Core membership is as follows (other staff members may be invited when necessary):
Training Manager
Training officer representative (HSST & scientists)
Training officer representative (STP)
Training officer representative (Route 2 CS)
Training officer representative (Technical)
Following the merge with MFT there have been several ad hoc cross-site training meetings and this will continue until a unified training team is created.

Information Technology Meeting – meets biweekly and core membership is as follows:
Head of Genetic Laboratories
Head of IT
Technical Lead for IT
Technical Section Head
Bioinformatician

Following the creation of the NWGLH many cross-site meetings have been, and continue to be, held on an ad hoc basis to support the transfer and merge of services, equipment, quality, finance, training etc. to ensure that the clinical service offered by the laboratories continues undisrupted and that the two sites become increasingly integrated.

Laboratory Working Groups and Regular Meetings

Programme Managers meeting – meets once a month and core membership is as follows:
Germline Programme Manager
Acquired Programme Manager
Metabolic/Respiratory Team Lead
Neurogenetics Team Lead
Learning Difficulties Team Lead
Pregnancy/Fertility Team Lead
Haemato- Oncology/ Solid Tumours Team Lead
Technical Programme Manager

Team Meetings – at least every two months the following team meetings and/or huddles occur with all staff within the team invited to attend:
Metabolic/Respiratory Team
Neurogenetics Team
Fertility Team
Haemato- Oncology/ Solid Tumours Team
Technical Team
Development Team

Joint Genetics Service meeting – this takes place bimonthly and is open to all staff. The meeting is chaired by the Head of Lab with contributions from senior laboratory and clinical staff and the quality team.

4 Management Requirements

4.1 Organisation and management responsibility

4.1.1 Organisation

The organisation and management of the North West Genomics Laboratory Hub – Liverpool Site are detailed in section 3 of this quality manual.

To ensure confidentiality of information the trust sets annual compulsory training in Information Governance and has the following policy: Information Governance Policy, which can be found on the trust intranet.

4.1.2 Management responsibility

4.1.2.2 Needs and requirements of users

The needs of the users are kept under constant review through a variety of mechanisms. The heads of the laboratory meet regularly with the Clinical Director from the clinical genetics service. The needs of other users are met through a programme of questionnaires coordinated by the quality leads.

Haematology users of the Cytogenetic service meet monthly through the Multidisciplinary Disease forums. A senior member of staff attends the Cancer Network Meeting. There is a biennial meeting of the Hematological Oncology Diagnostic Service (HODS) Group, attended as required.

There is a biennial meeting with Obstetric Users and the head of laboratory also attends the pathology clinical network group meeting as required. A representative from the neuro team attends Neurogenetics MDT at Alder Hey monthly. The Clinical Scientists of the Pregnancy and fertility section attend the weekly Fetal Medicine MDT meeting.

The website and the UKGTN website provide information on the molecular genetic tests for single gene disorders available within the department (please note this website has not been updated since April 2018). Enquiries to individual laboratories are required for the most accurate information.

As part of the National reconfiguration process in 2018-2019, the UKGTN has been replaced by the reconfiguration process and information is produced by the NHS England test directory.

They are translated into requirements that form the focus of objective setting and planning (4.15) within in the quality management system. Assessment of user satisfaction and complaints (4.15) is conducted on a regular basis and consideration of the findings form part of the annual management review (4.15).

4.1.2.3 Quality policy

The Quality policy of the North West Genomics Laboratory Hub – Liverpool Site is detailed in section 2 of this quality manual.

4.1.2.4 Quality objectives and planning

The Scientific Director, Head of Genetics, Quality Manager and the Quality Leads define the quality objectives of the laboratory and are responsible for ensuring that plans are made to meet these objectives. The management review (4.15) that is undertaken on an annual basis determines whether the objectives have been successfully completed and provides an

opportunity for revising such objectives and plans and the functioning of the quality management system. The management reviews can be found on iPassport.

4.1.2.5 Responsibility, authority and interrelationships
Detailed above in section 3.3.

4.1.2.6 Communication
Detailed above in section 3.4.

4.1.2.7 Quality Manager
The Quality Manager works with the Head of the Liverpool Service and Quality Leads to ensure the proper running of the Quality Management System for the NWGLH- Liverpool Site.

4.2 Quality Management System
4.2.1 General Requirements
The Laboratory has established, documented, implemented and maintained a quality management system within iPassport and on the shared drive (located here: S:\Genetics Labs\Quality Management\Quality Management System). The components and relationship within the quality management system are described in section 4 of this Quality Manual. The NWGLH – Liverpool Site has implemented a quality and audit schedule to ensure that all processes and procedures remain effective (located here: S:\Genetics Labs\Quality Management\Quality Management System\Audits). There is a developing methodology of audits and indicators. Where they fall short of expectation action is taken and documented in order to improve service outcomes, these will either be recorded on the Trust Ulysses system or the NWGLH – Liverpool Site non-compliance/quality improvement register (located here: S:\Genetics Labs\Quality Management\Quality Management System\Non compliances and QI).

4.2.2 Documentation Requirements
The quality management system documentation consists of the below which are all available on iPassport:

- A quality policy (GEN 293) in section 2 above.
- Quality objectives agreed at the annual management review with planning and monitoring at the quality management group.
- A quality manual.
- Standard operating procedures (SOPs).
- Other documentation e.g. witness audits, competency forms.
- Records which are kept either on StarLIMS, on the shared drive or in paper format.
- A copy of ISO 15189 is kept by the Quality Leads.

4.2.2.2 Quality manual
This requirement is fulfilled by the production of this Quality Manual which contains the Quality Policy. All staff are required to read updates via the task function of iPassport.

4.3 Document control
This standard is fulfilled for the laboratory using iPassport for control and review of all policies and procedures. This is detailed in the GEN 3435: Document Control Policy.

4.4 Service Agreements
This standard is fulfilled by GEN 42229: Procedure for the establishment and review of formal agreements to provide Medical Genetics Laboratory Services on iPassport.

4.5 Examination by referral laboratories

4.5.1 Selecting and evaluating referral laboratories and consultants

These requirements are fulfilled by the procedure DNA export procedure (MG0046) available on iPassport.

4.5.2 Provision of examination results

Referral laboratories are expected as normal practice, to send the report directly back to the requesting consultant with a copy sent to the referral laboratory. The regional laboratory does not alter the report in any way and does not send out a report but logs receipt of the report on StarLIMs.

4.6 External services and supplies

This requirement is fulfilled by the Cytogenetics Equipment Management Procedure (CY 32317) and Equipment & Materials Management Policy (MG0029). These are due to be merged into one policy.

All licensed service providers are assessed annually using the GEN 316: 'Supplier Contract – Service provision, Consumables and Third Party Agreements including Maintenance Contracts' form.

The purchasing of equipment and services for the Genetics Laboratory is managed by the equipment leads. They ensure compliance with legislation, availability of service contracts and continued provision of spare parts etc. Assessment and selection of new equipment is carried out by senior and principal members of the department, in consultation with the Technical Programme Manager. Whenever possible, new equipment is trialed by the department and tested prior to selection and purchasing to ensure the equipment meets the specifications.
Trust business cases are developed to justify the purchase of major equipment and assist the procurement process.

A list of selected and approved suppliers is available on the shared drive.

All information relating to equipment is kept on the shared drive. This includes records of maintenance, service and repair, instrument failure and corrective action and potential replacement time/cost. An inventory of all equipment that includes name of manufacturer, serial number, date of purchase and a record of contracted maintenance is maintained on the shared drive.

Majority of decontamination of equipment is carried out by the service provider and an EBDS certificate is provided, and stored on the shared drive. Any decontamination carried out by the department prior to servicing is recorded using forms available on iPassport and completed copies are stored on the shared drive.

Purchasing of new and replacement equipment is organised on an annual basis by the head of laboratory. This is reported to and monitored by the Genetics Directorate. The MFT policy 'Procurement of Goods and Services' can be consulted for further guidance.

4.7 Advisory services

Details of how users can contact the department are available on the trust website, the referral card (GEN 686) and user leaflet (GEN 785), found on iPassport (and available to users from the website).

4.8 Resolution of complaints

Department follows the trust policy regarding complaints & Trust documentation is used to annotate investigations. Trust Policy 'Compliments, Concerns and Complaints' can be found on MFT intranet.

4.9 Identification and control of nonconformities

The laboratory carries out a root cause analysis on all incidents and non-conformities to aim to reduce risks and improve procedures. The laboratory also has an annual audit schedule which is carried out by scientists and technologists to monitor the effectiveness of areas of service, policy changes, new techniques etc. and to suggest changes when appropriate, to improve the overall service to patients and service users. Staff are encouraged to continually look for areas where the service can be improved.
The requirement is fulfilled using the following policies and forms:
Ulysses Safeguard online incident reporting system
GEN 603: Laboratory incident policy
GEN 42233: Laboratory Audit and Continual Improvement Procedures
GEN 84: Quality Improvement
GEN 85: Incident and Non-conformance report

4.10 Corrective action

This requirement is fulfilled by the Laboratory Audit and Continual Improvement Procedures GEN 42233.

4.11 Preventive action

This requirement is fulfilled by the Laboratory Audit and Continual Improvement Procedures GEN 42233.

4.12 Continual improvement

This requirement is fulfilled by the Laboratory Audit and Continual Improvement Procedures GEN 42233.

4.13 Control of records

This standard is fulfilled by the following documents:
GEN 677: Genetics Record Control
CY2880: Cytogenetics Record Control Policy
MG0002: Molecular Genetics Record Control policy

4.14 Evaluation and audits

4.14.1 General

This requirement is fulfilled by the Laboratory Audit and Continual Improvement Procedures GEN 42233 and Laboratory audit and review policy MG0132.

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

Each request is reviewed by the relevant Duty Scientist/Lead Scientist for the disease to ensure that the appropriate analysis is carried out based on the clinical information provided.
Sample requirements are reviewed as documented procedures are reviewed.
Previously, suitability of procedures was reviewed based on best practice guidelines published by the professional bodies, on other publications and/or review of EQA reports.

However, the laboratory is now required to offer the tests/services indicated in the National Genomic Test Directory which is provided by the NHS Genomic Medicine Service, NHS England. The NHS Genomic Medicine Service will use a panel of experts to review suitability of tests and procedures on an annual basis.

4.14.3 Assessment of user feedback

This requirement is fulfilled via the use of user satisfaction surveys. User comments are recorded, reviewed and acted upon where appropriate. See also sections 4.7 and 4.8.
This standard is fulfilled by procedures:
GEN 3434: User satisfaction Policy
GEN 42233: Laboratory Audit and Continual Improvement Procedure
MFT Trust Policy: Compliments, Concerns and Complaints

4.14.4 Staff suggestions

NW-GLH encourages all staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions can be made directly to their line managers either privately or at meetings where it is recorded in the minutes with details of an evaluation. There is also a staff suggestion box in the corridor which is checked prior to operational meetings and discussed at the Departmental meetings and the joint lab meeting. The staff suggestions made throughout the year are compiled and presented in the Annual Management Review.

4.14.5 Internal Audit

The laboratory plans a schedule of audits to ensure compliance with ISO15189 standard and the requirements of the departments' policies and procedures. The audit schedule aims to provide assurance that agreed procedures have been implemented, are effective and have been maintained.
The requirements of this clause are fulfilled by the following procedures:
GEN 42233: Laboratory Audit and Continual Improvement Procedures

4.14.6 Risk Management

The organisation's risk management activity is overseen by the Risk Management Committee and, ultimately, the Group Board of Directors, and follows the trust Risk Management Strategy and Policy (available on MFT Intranet). This Trust Policy fulfills the requirements of this clause.

4.14.7 Quality Indicators

The laboratory carries out systematic evaluation and audit of their performance based on quality indicators that are seen as critical to the success of the service. They have been developed to provide assurance to all that the quality of the service has been maintained, help identify areas where improvements could be made and prevent failing processes. The aim of the quality indicators is to ensure current levels of patient safety and to improve them in the longer term.
The performance of the QMS is also monitored and maintained via key performance indicators (KPIs) presented at the monthly Quality Meeting.
The results and interpretation of these evaluations and audits will be made available to staff and users as required, and will form part of the annual management review.
Further details can be found in GEN 685: Performance Monitoring

4.14.8 Reviews by external organisations

The Genetics laboratory is assessed by United Kingdom Accreditation Service (UKAS). The assessment process is based on a 4-year cycle with full on-site assessment done in year one followed by an agreed programme of visits and assessments. The laboratory will create a plan to resolve all improvement actions with the aim of resolving all findings within the time frame stipulated by UKAS.

The Quality Management Team will review the report and subsequent actions to provide assurance that the requirements of ISO15189 have been met will continue to be met.
Further details can be found in:
Laboratory Audit and Continual Improvement Procedures GEN 42233 and GEN 3433: External Quality Assurance Policy

4.15 Management Review

The Quality Management Team conduct an annual review and produce a report. It considers the items detailed in the agenda GEN 469: Management Review Agenda.

A review of key objectives for the subsequent year is included and new objectives for the upcoming year are defined and plans formulated for their implementation.

4.15.2 Review Input

The Genetics Laboratory organise and contribute to several meetings which are detailed in section 3.4 above. The aim of these meetings is to review the service and progress and specific actions with the aim of improving the service provided to users, becoming more effective, improve productivity and prevent patient harm that may arise from its services.
With this aim, the Genetics Laboratory produces KPI reports (three monthly), which are presented at the Quality Meeting and Joint Team Meeting and reviewed in line with GEN 685 Performance Monitoring policy. Key incidents and trends are discussed and monitored through the monthly Clinical Effectiveness meeting.

4.15.3 Review activities

The Genetics Laboratory reviews workload, turnaround times, non-compliances and incidents to identify trends and patterns which inform our preventive actions. The quality and appropriateness of the laboratory's contribution to patient care is evaluated by the senior management team monthly at the Senior Operational Meeting, held at the Manchester Site. The laboratories KPI's are reviewed by the Head of Service and the Programme Managers. These are presented at team meetings, the quality meeting and joint laboratory meetings.

5 Technical Requirements

5.1 Personnel

5.1.1 General

The laboratories use the relevant Trust policies and procedures issued by the Personnel Deparment for staff recruitment and selection, and for grievance and staff disciplinary matters.

5.1.2 Professional Qualifications

Personal qualifications are documented in the person specification part of the job description for each role. All person specifications are held on iPassport.
For current staff, qualifications and ongoing registration with relevant professional body is reviewed annually at PDR.

5.1.3 Job descriptions

All staff have contracts issued by the Trust Personnel Dept. and job descriptions issued by the laboratory using Trust conditions and reviewed accordingly. Generic job descriptions are held on iPassport and more specific job descriptions held in personal files.

5.1.4 Personnel introduction to the organisational environment

All staff participate in the Trust induction programme, which is evidenced on ESR. In addition, the laboratory has its own induction procedures and forms which are held on iPassport:
GEN 497: Induction Policy
GEN 478: Local Induction checklist
GEN 754: Induction checklist (first day)
GEN 478: Local induction checklist

5.1.5 Training

There is a training programme for all members of the staff outlined in the Genetics Laboratory Training Policy (GEN 779) and all staff have access to appropriate library and information services.

Training is organised into the following areas and covered by separate training policies:

- **Clinical Scientist training** (Policy GEN 775). This covers departmental training for State Registered Clinical Scientists, trainee Scientists (both STP and Route 2), and Higher Specialist Training for Scientists (HSST).
- **Genetic Technologist training** (Policy GEN 784) This outlines current training arrangements for Healthcare Science Associates / Practitioners /Senior Practitioners.
- **Competency Assessment** (Policy GEN 789) The purpose of this document is to comply with the requirements of the ISO15189 standards 5.1.5, 5.1.6, 5.1.7, 5.1.8, and 5.1.9. It describes laboratory policy and procedure for competency assessment and re-assessment.

In addition, the laboratory also has a Scientific Administration Officer Training Policy GEN 307.

5.1.6 Competence assessment

The laboratory process for assessing and monitoring ongoing competency is outlined in a separate policy (Laboratory Competency Policy GEN 789) and details the requirements necessary to fulfil ISO 15189 standards. It describes laboratory policy and procedure for competency assessment and re-assessment.

This will cover a broad range of laboratory techniques, analytical workflows and management duties to assess the competency of staff to perform tasks relating to their role, safely and to an acceptable standard. Competency to perform a task or function is assessed following satisfactory completion of training. In addition, continued competency or performance is monitored through day to day activities which may include examination of work records or witness examination audits and is reviewed annually at appraisal. Reassessment and/or retraining may also take place if indicated by a non-compliance or incident, or if the individual has not performed the task for over 6 months due to long term absence (i.e sickness/maternity).

5.1.7 Reviews of staff performance

It is mandatory that all staff take part in the annual Trust Personal Development Review (PDR) programme. The paperwork is designed and provided by the trust and is available on the trust intranet.

Participation is evidenced on ESR. This is reported monthly and is RAG rated, expectation is to be over >90% compliance.

5.1.8 Continuing education and professional development

All senior staff above Band 8b take part in the RCPath CPD scheme. All other scientific and technical staff take part in an internally organised CPD scheme.

The laboratory maintains a training budget including support for attendance at meetings and conferences. Participation in national meetings is also encouraged, and feedback from these meetings is presented to the whole department.
All staff have access to appropriate library and information services.
The laboratory 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.

5.1.9 Personnel Records

Personal files are held in the Administration Office and meet the requirements a) to e) and h) to k) and in accordance with the trust policies. Records are kept of staff attendance, annual leave and sickness.
Training and competency records (requirements f) and g) are held in staff members Personnel files and CPD files. Copies of staff member's educational qualifications are kept in their CPD files.

5.2 Accommodation and environmental

5.2.1 General

The NHGLW – Liverpool Site is located on the second floor of the Jeffcoate wing of the legal entity Liverpool Women's NHS Foundation Trust. Separate office and laboratory space is provided with defined areas.

5.2.2 Laboratory and office facilities

Access to the department is limited to authorised staff only using proximity cards. Access to information systems which contain personal information is controlled using usernames and passwords.
The main forms of communication are either face-to-face meetings, e.g. Lab meeting, or MS Outlook email system.
Safety facilities are regularly tested:

- Fire alarms; weekly
- Fire extinguishers; annually

- Power systems; monthly

5.2.3 Facilities for storage

Specimens and reagents are stored in defined areas within the laboratory working areas as not to contaminate each other. There are dedicated storage facilities for acids and solvents.
The cultured cell bank is housed in the designated room for the storage of cells in liquid nitrogen within the Reproductive Medicine Unit.
Patient records and laboratory documentation are kept in secure cabinets or secure offices and on the laboratory databases. Current Patient records are kept in locked steel filing cabinets.
Please also refer to GEN677: Genetics Record Control Policy.

5.2.4 Staff Facilities

Suitable facilities are available for staff within the laboratories including male and female toilets, secure locker space, and a rest room with basic catering facilities.

5.2.5 Patient sample collection Facilities

Not applicable to the laboratory.

5.2.6 Facility maintenance and environmental conditions

The laboratories provide a safe working environment in accordance with current legislation. The Laboratory is maintained by Liverpool Women's NHS Foundation Trust Estates department and is covered by a SLA. All office areas are cleaned daily by the Trust Facilities Department and the laboratory areas by laboratory staff. Please also refer to GEN780: Cleaning and Decontamination Policy.
Many areas are kept at optimal temperature using air conditioning units. Furthermore, laboratory staff monitor room temperature and humidity where required to ensure quality of examinations.

5.3 Laboratory equipment, reagents and consumables

5.3.1 Equipment

5.3.1.1 General

The purchasing of equipment and services for the Genetics Laboratory is managed by the equipment leads. They ensure compliance with legislation, availability of service contracts and continued provision of spare parts etc.
Assessment and selection of new equipment is carried out by senior and principal members of the department, in consultation with the Technical Programme Manager. Whenever possible, new equipment is trialed by the department and tested prior to selection and purchasing to ensure the equipment meets the specifications.
Trust business cases are developed to justify the purchase of major equipment and assist the procurement process.

A list of selected and approved suppliers is available on the shared drive.

All information relating to equipment is kept on the shared drive. This includes records of maintenance, service and repair, instrument failure and corrective action and potential replacement time/cost. An inventory of all equipment that includes name of manufacturer, serial number, date of purchase and a record of contracted maintenance is maintained on the shared drive.

Majority of decontamination of equipment is carried out by the service provider and an EBDS certificate is provided, and stored on the shared drive. Any decontamination carried out by

the department prior to servicing is recorded using forms available on iPassport and completed copies are stored on the shared drive.

Purchasing of new and replacement equipment is organised on an annual basis by the head of laboratory. This is reported to and monitored by the Genetics Executives and escalated to the trust Capital Planning Committee for equipment over £5K.

This requirement is fulfilled by the CY 32317: Equipment management procedure
And MG0029: Equipment and Materials management policy

5.3.1.2 Equipment acceptance testing
This requirement is fulfilled by the CY 32317: Equipment management procedure, MG0029: Equipment and Materials management policy and GEN 499 Validation and Verification Policy.

5.3.1.3 Equipment Instructions for use

This requirement is fulfilled by the CY 32317: Equipment management procedure, MG0029: Equipment and Materials management policy and GEN 3435: Document Control Policy

5.3.1.4 Equipment calibration and metrological traceability
This requirement is fulfilled by the GEN 512: Uncertainty of Measurement Policy

5.3.1.5 Equipment maintenance and repair
This requirement is fulfilled by the CY 32317: Equipment management procedure
And MG0029: Equipment and Materials management policy

5.3.1.6 Equipment adverse incident reporting
When appropriate, adverse incidents relating to equipment are reported to the manufacturer and Medicines and Healthcare Products Regulatory Agency (MHRA).
This requirement is fulfilled by the CY 32317: Equipment management procedure
And MG0029: Equipment and Materials management policy

5.3.1.7 Equipment records
This requirement is fulfilled by the CY 32317: Equipment management procedure and MG0029: Equipment and Materials management policy

5.3.2 Reagents and consumables
5.3.2.1 General
This requirement is fulfilled by the:

- GEN 520: Receipt and Distribution of Stock to Genetics Laboratories
- CY 32324: Audit Trail Procedure
- MG481: Reagents & Consumables Record
- GEN 913: Receipt of Laboratory Consumables and Acceptance of Use

5.3.2.2 Reagents and consumables – Reception and storage
This requirement is fulfilled by the:

- GEN 520: Receipt and Distribution of Stock to Genetics Laboratories
- CY 32324: Audit Trail Procedure
- MG481: Reagents & Consumables Record
- GEN 913: Receipt of Laboratory Consumables and Acceptance of Use=

Specimens and reagents are stored in defined areas within the laboratory working areas. There are dedicated storage facilities for acids and solvents, and a separate secure store external to the main buildings.

The entire department is protected by an alarm with a direct link to the 'Front of House'. Details are provided in the following procedures:

- GEN 771: Clinical Control Policy
- GEN 42232: Moving of Chemical Stocks and Waste Procedure
- CY 32298: Waste Disposal Procedure

5.3.2.3 Reagents and consumables – Acceptance testing
This requirement is fulfilled by GEN 913: Receipt of Laboratory Consumables and Acceptance of Use, along with CY 32324: Audit Trail Procedure and MG481: Reagents & Consumables Record.

5.3.2.4 Reagents and consumables – Inventory management
This requirement is fulfilled by the: MG481: Reagents & Consumables Record and CY 32312: Laboratory Ordering Procedure.

5.3.2.5 Reagents and consumables – Instructions for use
Instructions for use are generally provided with the kit and are available for all staff to access via ipassport. There is an increasing trend to make kit inserts available via the internet. All staff have access to the internet.

5.3.2.6 Reagents and consumables – Adverse incident reporting
Incidents relating to reagents and consumables are reported to the manufacturer and Medicines and Healthcare Products Regulatory Agency (MHRA).
This requirement is fulfilled by GEN 913: Receipt of Laboratory Consumables and Acceptance of Use, along with CY 32324: Audit Trail Procedure and MG481: Reagents & Consumables Record.

5.3.2.7 Reagents and consumables
This requirement is fulfilled by the CY 32324: Audit Trail Procedure and MG481: Reagents & Consumables Record.

5.4 Pre-examination Processes

5.4.1 General
All pre-examination processes are documented and are available to all staff via the iPassport Quality Management System.

5.4.2 Information for users and patients

GEN 785 Genetics Laboratory User Leaflet.
The leaflet and information on genetic services are also available through the Hospital website:
https://www.liverpoolwomens.nhs.uk/health-professionals/genetic-laboratory-services/
and on further molecular genetics tests on the UKGTN www.ukgtn.nhs.uk and Orphanet www.orpha.net websites.

5.4.3 Request form
This standard is fulfilled by GEN 686: Genetics referral card
Where specific information is required to perform a test there is a specific request form for that test, all are held on ipassport and available to users on request.

5.4.4 Primary Sample collection and handling
5.4.4.1 General

The laboratory is not directly involved in the collection specimens but offers sample type, volume and collection & transportation Guidance, available on the laboratory web site:
GEN 1: Sample Collection & Transportation Guidance
GEN 686: Genetics referral card

5.4.4.2 Instructions for pre-collection activities
This standard is fulfilled by GEN 1: Sample Collection & Transportation Guidance

5.4.4.3 Instructions for collection activities
This standard is fulfilled by GEN 1: Sample Collection & Transportation Guidance and MG0039: Buccal cell sampling (Cheek scrapes) for Molecular Genetic testing.

5.4.5 Specimen transportation
The laboratories do not control or manage the transport of specimens, however guidance is offered in the document GEN 1: Sample Collection & Transportation Guidance which is available via the laboratory website.

5.4.6 Specimen reception
This standard is fulfilled by:
- GEN 573: Genetics Sample Reception
- CY 32304: Specimen Transport and Reception procedure
- CY 689: Blood Sample Receipt
- MG0043: Specimen reception and booking in procedure
- MG 310: Inappropriate/Duplicate sample procedure
- MG0044: Leaking sample procedure
- MG0045: High risk sample procedure

5.4.7 Pre-examination handling, preparation and storage
The requirements of this clause are met by GEN 771: Clinical Control Policy.

5.5 Examination procedures
Selection and validation of examination procedures (5.5)

c) Genetics
This standard is fulfilled by procedures:
GEN 499: Validation and Verification Policy
GEN 511: Uncertainty of Measurement Procedure
GEN 512: Uncertainty of Measurement Policy
GEN 766: Change Management Procedure

5.5.1 Selection, verification and validation of examination procedures
5.5.1.1 General
North West Genomics Laboratory Hub – Liverpool Site meets the requirements of this clause

5.5.1.2 Verification of examination procedures
Equipment, C.E. marked products and kits and associated procedures are verified by the laboratory before being introduced in to routine use.
Before being introduced the procedure will be signed off by a senior member of staff. The procedure is documented by GEN 499: Validation and Verification Policy

5.5.1.3 Validation of examination procedures
The Genetics Laboratory validates examination procedures derived from the following sources:
- Non-standards method
- Laboratory designed or developed method

- Standard methods used outside their intended scope
- Validated methods which have subsequently been modified

Validation documentation is held on iPassport. Prior to this system, hardcopies are kept in Room 2806.

5.5.1.4 Measurement of uncertainty of measured quantity values

Overarching guidance is provided in the documents GEN 511: Uncertainty of Measurement Procedure and GEN 512: Uncertainty of Measurement Policy.

The NHGLH – Liverpool Site accepts the principle and requirement for measurement of uncertainty within our scope of practice. This has been considered for all processes within the laboratory, see appendix A of GEN 512: Uncertainty of Measurement Policy.

5.5.2 Biological reference intervals or clinical decision values

Clinical decision values are within specific diseases profiles and relevant protocols.

5.5.3 Documentation of Examination procedures

All examination procedures are carried out in accordance with the section specific SOPs and Policies. A full record of these is kept on the iPassport database. All procedures and policies are reviewed regularly and are under full document control. Examination procedures are written following the GEN 3435: Document Control Policy which meet the requirements of this clause.

5.6 Ensuring the quality of examination results

5.6.1 General

All procedures, pre and post examination, are carried out by staff who follow pre-defined procedures that are available on iPassport. The laboratory will not fabricate any results.

5.6.2 Quality Control

5.6.2.1 General

The laboratory has defined a variety of procedures to guarantee the quality of reports to service users and ensure patient safety, including audit and regular competency assessment.

5.6.2.2 Quality control materials

This standard is fulfilled by MG0120: Internal quality control policy.

5.6.2.3 Quality control data

This standard is fulfilled by MG0120: Internal quality control policy, CY 32303: Chromosome Analysis and Karyotyping Procedure and CY 642: Microarray Infinium CytoSNP 850K Analysis & Reporting.

5.6.3 Interlaboratory comparisons

5.6.3.1 Participation

The laboratories will take part in all recognised EQA schemes relevant to the services they provide.

5.6.3.2 Alternative approaches

If no scheme is available a sample swap could be carried out with a relevant laboratory where appropriate.

5.6.3.3 Analysis of interlaboratory comparison samples

This standard is fulfilled by procedure: GEN 3433: External Quality Assurance Policy

5.6.3.4 Evaluation of laboratory performance
The laboratory will conduct a formal review of their EQA performance as results are returned via an EQA review form (GEN836) and annually during the Annual Management Review. The results are made available to all their staff and to the directorate management and quality group. The laboratories will implement changes to improve their performance where indicated.

5.6.4 Comparability of examination results
Not applicable.

5.7 Post-examination Processes
5.7.1 Review of results
This standard is fulfilled by the following documents:
- MG0121- Checking and reporting results Policy
- CY 32288 – Cytogenetics Checking and Authorising Procedure
- CY 642: Microarray Infinium CytoSNP 850K Analysis & Reporting

5.7.2 Storage, retention and disposal of clinical samples
This standard is fulfilled by the following documents:
- CY 32289: Clinical Material Control Procedure
- MG0003: Clinical Material Control Policy
- MG0126: DNA Storage Inventory

5.8 Reporting results
5.8.1 General
North West Genomics Laboratory Hub – Liverpool Site endeavors to report results in a manner that is accurate, clear and unambiguous and in accordance with CY 2587: Reporting procedure and MG0121: Checking and Reporting Results Policy.

The format of the report is defined in the Laboratory Information Management System, StarLIMS.
Reports can be in an electronic format, paper format or both. Electronic reports are reported as pdfs via secure email or onto the HODS database according to the procedures CY 2587: Reporting procedure and MG0121: Checking and Reporting Results Policy.

5.8.2 Report attributes
The department meets the requirements of this clause.

5.8.3 Report content
The department meets the requirements of this clause.

5.9 Release of results (4.7, 5.8, 5.9)
5.9.1 General
This standard is fulfilled by procedure:
CY 2587: Reporting procedure.
MG0121: Checking and Reporting Results Policy

5.9.2 Automated selection and reporting of results
This clause is not applicable to NWGLH – Liverpool Site.

5.9.3 Revised reports
The department meets the requirements of this clause.

5.10 Information Management (5.10)
5.10.1 General
The Trust's Chief Information Officer (CIO), Head of IT and IT support staff deal with all aspects of data and information technology, supported by the Trust's Information Governance Manager and the departmental Information Governance / IT Lead. The CIO is responsible for ensuring that the IT Department and users of IT systems comply with all applicable requirements of the data protection standards and other regulations.
The information technology requirement is provided by Liverpool Women's NHS Foundation Trust; however, processes are ongoing to transfer genetics databases from LWH servers to MFT following the merge in August 2019.

5.10.2 Authorities and responsibilities
The Information Asset Owner and Departmental StarLIMS Administrators (LIMS Forum members) are jointly responsible for maintaining the system and as such have administrator rights in conjunction with the software provider StarLiMS UK.

An authority for access to data and various data analysis is controlled by the permissions system linked to individual login usernames and passwords.

5.10.3 Information system management
Changes to StarLIMS can be requested by any member of staff by placing a suggestion on the LIMS forum whiteboard on the Genetics Labs shared drive. These will then be discussed in the LIMS forum. A change request form is filled out and the suggestion evaluated, and a specification agreed. If approved the change is then implemented in the training/test system by the Starlims Lead and verified before going live.

The following SOPs are applicable to IT management within the laboratory:
Overarching policy: GEN 682: Data Management & Storage Policy

StarLIMS Database Procedures
- GEN 553: Genetics Laboratory StarLiMS User Guide

Karyotyping Imaging Procedures:
- CY 31423: Image Analysis Database Procedure
- CY 637: Using Cytovision - Karyotyping Basics
- CY 32311: CytoVision Scanning & Karyotyping Systems
- CY 32303: Chromosome Analysis and Karyotyping Procedure

iPassport Procedures:
- GEN 3435: Document Control Policy

Also refer to appropriate iPassport Documentation and guides which are available on iPassport.

CLC Procedures:
- MG 513: Variant analysis for NGS
- MG 673: CLC Coverage Analysis

Bluefuse Multi: all support info is embedded into Bluefuse Multi database.

Trust Policies on IM&T and Information Governance Can be found on the trust intranet

In addition, the information activities of the laboratory must abide by the following legislation:

- Data Protection Act
- Regulation of Investigatory Powers Act
- Computer Misuse Act
- Freedom of Information Act

The servers are fully virtualized UCS Mini Blade chassis and are located in the Trust Data Centre. The centre is only accessible to authorised Trust IT and Estates staff. The centre is environmentally controlled and temperature monitored to ensure the integrity of data and information on the servers. All Trust servers are backed up nightly and copied over to a failover site in at AIMES Tier 3 Data centre, ensuring the safety of all Trust data in the event of an incident onsite.

The Liverpool Women's NHS Foundation Trust IT Department is accredited to the below standards:

Cyber essentials plus
ISO27001
ISO9001
ISO22301

The department has a contingency plan, GEN 782: Business Continuity Plan - Genetics Laboratories, to maintain services in the event of failure or prolonged downtimes.