

**QUALITY MANUAL**

**GENOMIC DIAGNOSTICS LABORATORY**

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1. **PURPOSE**

This Quality Manual is consistent with the requirements of ISO 15189:2012 standards, clause 4.2.2.2. It fulfils two functions. Firstly it describes the Quality Management System for the benefit of the laboratory’s own management and staff, and secondly it provides information for users and for inspection/accreditation bodies.

1. **GENERAL INFORMATION**
   1. **The Genomic Diagnostics Laboratory**

The Genomic Diagnostics Laboratory (GDL) comprises two major laboratory sections –Biochemical Genetics (also known as the Willink Laboratory) and the joint Cytogenetics, Molecular Genetics and Specialised Cell Culture Services section. It is part of the Manchester Centre for Genomic Medicine (MCGM), a directorate within St Mary’s Hospital, which is a division of the Central Manchester University Hospitals NHS Foundation Trust.

The GDL provides services predominantly for the North-West population including East Lancs., South Cumbria, Greater Manchester and North-East Cheshire, but also provide some services nationally and internationally. Tests are undertaken on a variety of different tissues including blood samples, amniotic fluid, chorionic villus, post mortem samples, urine, skin samples, and tumour samples (see the **Manchester Centre for Genomic Medicine (MCGM)** website [www.mangen.org.uk](http://www.mangen.org.uk) for more details).

The laboratories also collaborate closely with two international EQA schemes which operate from within The Manchester Centre for Genomic Medicine; The European Molecular Genetics Quality Network (EMQN; [www.emqn.org](http://www.emqn.org)) and the European Research Network for evaluation and improvement of screening, Diagnosis, and treatment of Inherited disorders of Metabolism (ERNDIM; [www.erndim.org](http://www.erndim.org)).

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* 1. **GDL Documentation Hierarchy**

The GDL documentation is held within the laboratory quality 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). This Quality Manual describes the Quality Management System of the GDL (ISO 4.2.2.2). 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 Working Instructions (standard operating procedures, SOPs; MP000 051) for technical processes are not described in this manual but can be found in Q-Pulse in the ‘Diagnostic’ folder (see section 4.3). These SOPs may contain the specific quality requirements, technical requirements and working instructions for the specific procedure. In addition, Q-Pulse is used to store Quality Records such as test validation documents, laboratory audit forms, instruction manuals and meeting minutes.



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

* 1. **The Quality Manual**

The sections of the quality manual are arranged so that they equate with the ISO 15189:2012 Standards (DOC3046). Under the title of each standard there is a brief description of the way in which the GDL seeks to comply with the particular standard clause and references are given to appropriate policies and/or procedures (either Trust intranet or GDL Q-Pulse procedures (in square brackets)).

Section 4 describes the management requirements (including the organisation of the GDL and its quality management system) and section 5 describes the technical requirements (including personnel, resources, pre-examination, examination and post-examination processes).

1. **QUALITY POLICY**

The Quality Policy (ISO clauses 4.1.2.3 & 4.2.2a) of the GDL is given overleaf and published as a separate controlled document [DOC1018] displayed within the laboratory and accessible from Q-Pulse.

**QUALITY POLICY**

**GENOMIC DIAGNOSTICS LABORATORY**

The Genomic Diagnostics Laboratory (GDL) comprises two major sections reflecting diverse work streams - the Biochemical Genetics, section (also known as the Willink laboratory) and the joint Cytogenetics, Specialised Cell Culture Services and Molecular Genetics section. It is part of the Manchester Centre for Genomic Medicine– a directorate within St Mary’s Hospital which, in turn, is part of Central Manchester University Hospitals NHS Foundation Trust.

The goal of the GDL is to provide the highest quality diagnostic service to our patients.

Commitment to Quality

It is the policy of the GDL to report the correct genetic diagnosis on the correct patient in an appropriate timeframe using reliable and accurate tests utilising the most relevant technology, and to communicate that diagnosis to the correct clinician in the most effective way.

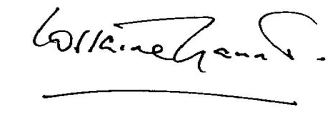
The GDL Management is committed to:

* patient care, reporting clinically useful test results to service users
* respecting patient confidentiality
* innovation and the development of new technologies ensuring state of the art testing
* delivering efficient service workflows, meeting all agreed national and local targets
* providing laboratory staff of all grades with the appropriate knowledge, skills, competency development and support for continued professional development (CPD) including key performance indicators such as annual appraisal, mandatory training, equality and diversity
* ensuring that all laboratory staff are familiar with the quality policy and understand what is expected from them

The GDL seeks to satisfy the UKAS ISO 15189 standards and will:

* set annual quality objectives, maintain a quality manual and complete an annual management review
* apply and promote all areas of the quality management system, including the use of documented procedures, internal audit, procurement and maintenance of equipment and other resources, as well as the health, safety and welfare of staff and visitors
* ensure the laboratory delivers the quality of service which this policy describes, within the resources available
* promote good professional practice and conduct as laid out in best practice guidelines and Trust procedures and comply with current legislation
* maintain a commitment to continual quality improvement including assessment of user satisfaction, external quality assessment, and the identification of non-compliance corrective and preventive actions

Signed on behalf of the GDL:



**GDL Director Date:** 05.11.2015

1. **MANAGEMENT REQUIREMENTS**
   1. **Organization and management responsibility**
      1. **Organization**

The GDL is part of the directorate of the Manchester Centre for Genomic Medicine within the Division of St Mary’s hospital and Central Manchester and Manchester Children’s University Hospitals NHS Trust (ISO 4.1.1.2). The internal organisational relationships are shown below in figure 2. The Manchester Centre for Genomic Medicine and the GDL (incorporating Regional Molecular Genetics, Regional Cytogenetics and Willink Biochemical Genetics laboratories) have a defined management structure.



**Figure 2: The relationship to the Host Organisation.** CMFT: Central Manchester University Hospitals NHS Foundation Trust; SMH: St Mary’s Hospital.

All new staff members are required to declare any conflicts of interest prior to commencement at the Trust. Existing staff members are requested annually by the Quality Manager to declare of any new conflicts of interests to the Trust (ISO 4.1.1.3) [Trust policy ON8-2880 – Standards of Business Conduct & Hospitality Policy]. Staff members adhere to Trust and GDL requirements to maintain confidentiality [Trust policy ON4-3437 - Confidentiality Code of Conduct and Information Disclosure Policy; DOC2051] and ensure respectful treatment of human samples (ISO 4.1.1.3) [staff induction and training].

The Director of the GDL is a Consultant Clinical Scientist and has the responsibility for the services provided by the GDL supported by a Senior Management Team of consultant and principal clinical scientists (ISO 4.1.1.4). The duties and responsibilities of the laboratory director are documented below. These include professional, scientific, consultative or advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory. 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 laboratory.

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
* 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 (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 and Safety Team)
* Selects referral laboratories and monitor quality of service (designated Clinical Scientists and Quality Manager respectively)
* Selects and monitors laboratory suppliers (Equipment Team)
* Addresses complaints and suggestions (Quality Manager)
* Plans and directs research (Senior Management Team)
* Ensures a contingency plan for essential services (Quality Management Team)
  + 1. **Management responsibility**
       1. *Management 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, the quality policy, quality objectives, staff responsibilities, the appointment of a quality manager, annual management reviews, staff competency, and management of resources necessary for pre-examination, examination and post-examination activities.

* + - 1. *Needs of users*

Laboratory services, including appropriate advisory and interpretative services, are periodically reviewed to ensure that they meet the needs of patients and service users (ISO 4.1.2.2). Information is gathered via the use of satisfaction questionnaires (ISO 4.14.3) and in response to complaints or comments regarding the service (ISO 4.8). These can be translated into corrective or preventive actions and form the focus of objective setting and planning (ISO 4.1.2.4). Assessment of user satisfaction and complaint findings [DOC1187] forms part of the annual management review (ISO 4.15). The service profile of the GDL can be found on the MCGM website at [www.mangen.org.uk](http://www.mangen.org.uk), which also includes a Willink Laboratory Handbook.

* + - 1. *Quality policy*

The Quality Policy is regularly reviewed to ensure that it recognises the Trust values (pride, respect, empathy, consideration, compassion and dignity) and Trust objectives (patient safety and clinical quality, patient and staff experience, productivity and efficiency). It is communicated to all staff through Q-Pulse [DOC1018].

**4.1.2.4 Quality objectives and planning**

* + - 1. *Quality objectives and planning*

The Director and Senior Management Team define the quality objectives within the GDL (ISO 4.1.2.4) ensuring consistency with the quality policy. This team, in conjunction with the Quality Management Team, is responsible for ensuring that objectives are measurable. The quality objectives are available to all members of staff on Q-Pulse [DOC1343]. The progress of GDL quality objectives are reviewed regularly at various management meetings. The annual management review (see 4.15 below) is used by the Senior Management Team to determine whether objectives have been successfully completed and provides an opportunity for reviewing both GDL quality objectives and the integrity of the quality management system.

* + - 1. *Responsibility, authority and interrelationships*

The GDL is managed by the GDL Director with sections led by Consultant and/or Principal Clinical Scientists (ISO 4.1.2.5). The organisation of GDL staff is represented in the organisational chart (Figure 3). All staff and their roles are documented in GDL Staff Roles and Responsibilities document [DOC2072]. The specific roles and responsibilities of the Quality management team are described [DOC488].



**Figure 3: The organisation within the Genomic Diagnostics Laboratory.**

* + - 1. *Communication*

The GDL has different methods and means for communicating with staff including meetings (summarised below), newsletters, lunchtime seminars, and staff suggestions via a whiteboard and Q-Pulse register. Meeting minutes are available on Q-Pulse. Quality Management meetings are distributed to all staff members. Dashboards are available on shared network drives.

The GDL communicates with stakeholders via the MCGM website, letters, complaints, and user satisfaction questionnaires. Stakeholders are informed of any significant changes to services.

Regular MCGM and GDL meetings include:

1. The **MCGM 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

1. The **Genetic Medicine Clinical Effectiveness Committee** meets monthly. Its membership is as follows:

* Clinical Lead
* Genetics Risk Lead
* Divisional Clinical Governance Manager
* Clinical Representative for Biochemical Genetics
* Laboratory Representative for Biochemical Genetics
* Quality Manager of the GDL Laboratories / Laboratory Representative for Cytogenetics and Molecular Genetics
* Quality Manager of Clinical Genetics
* Clinical Research Lead
* Office Manager for Clinical Genetics
* Clinical Audit Lead
* 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.

1. The **Quality Management Team** meets every 3 months. Its membership is:

* Quality Manager
* Quality Leads
* Training Officer
* Document Control Lead
* Health & Safety Lead
* Audit Lead
* Equipment Lead

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].

1. The **Senior Management Team** of the GDL Laboratories meets fortnightly. Membership is as follows:

* Director of GDL
* All Clinical Scientists Band 8b and above including Head of Laboratory sections

1. The **Willink Unit Heads of Department Management Team** meets bimonthly. Its membership is as follows:

* Genomic Medicine Directorate Manager
* Clinical Lead for Genetics
* Lead nurse for Genetics
* Lead dietician for the Willink
* Willink Clinical Consultants

Notes of the meetings are circulated to members of the team and appropriate actions taken. Minutes are held by the secretary to the Willink Unit.

1. The **Willink Biochemical Genetics Operational Management Team** meets monthly. Its membership is as follows:

* Head of Willink Biochemical Genetics
* Sectional leads and deputies
* Quality and Risk Lead for Biochemical Genetics

Notes of the meetings are circulated to members of the team and appropriate actions taken.

In addition, all **Willink staff members** meet monthly [DOC729]. Due to the large size of the other laboratory areas the **Technical Team Leads** meets every month and includes the Technical Team Manager, Lead Technologists and Senior Genetic Technologist Team Leads [DOC2068]. 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 (search GDL for meeting).

* + - 1. *Quality manager*

There is an appointed Quality Manager (ISO 4.1.2.7) who works with Senior Management and the Quality Team to ensure that quality management system processes are established, implemented, and maintained. They report directly to the Director of GDL on the performance and effectiveness of the quality management system and any need for improvement. The Quality Manager also promotes of the awareness of the needs and requirements of service users by providing guidance to staff in seminars and meetings and through the means of user satisfaction surveys, suggestions and complaints.

The current post-holder is Dr Andrea Naughton. There is are three Quality and Risk Leads who can deputise for the Quality Manager; Ms Natasha Leo, specific area of responsibility is the Molecular and Cytogenetics service and Mr Alistair Horman and Mr Rob Gibson for Biochemical Genetics.

* 1. **Quality management system**
     1. **General requirements**

The components and relationships within the Quality management system (ISO 4.2) are described in section 4 and 5 of this Quality Manual. The roles and responsibilities of laboratory quality management in ensuring compliance with the ISO standards are defined below:

|  |  |
| --- | --- |
| **Role** | **Responsibility** |
| Director of GDL Laboratories | Overseeing compliance with ISO 4 & 5 |
| Consultant Clinical Scientists | Deputising for Director of Lab responsibilities |
| Principal Clinical Scientists / Section Leaders | Ensuring compliance with ISO 5.4 to 5.9 |
| Quality Manager(s) | Implementing, maintaining and reporting on function and effectiveness of the Quality Management System (including liaising with inspection bodies) ISO 4 & 5 |
| Training Officer | Ensuring compliance with ISO 5.1 |
| Health & Safety Officer | Ensuring compliance with ISO 5.1.4 |
| Document Control Lead | Ensuring compliance with ISO 4.2.2 |
| Audit Lead | Ensuring compliance with ISO 4.14 |
| Equipment Lead | Ensuring compliance with ISO 4.6, 5.31 |

Table 1: Roles within the Quality Management system.

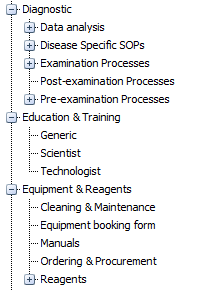
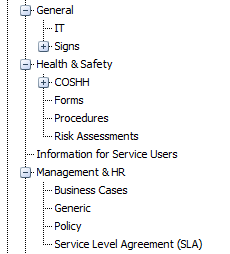
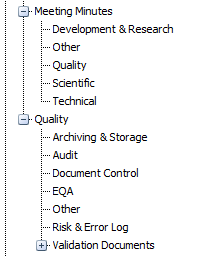
The Quality Management Team meets to discuss the strategy of the quality management system and to monitor, evaluate and improve the effectiveness of the quality management system.

* + 1. **Documentation requirements**

The GDL has controlled regularly reviewed documents on Q-Pulse pertaining to a quality policy [DOC1018], quality objectives [DOC1343], quality manual [DOC1191] and the annual management review [DOC1020]. This quality manual describes the scope of the quality management system and fulfils the requirement of ISO 4.2.2.2.

* 1. **Document control**

GDL documents are controlled using Q-Pulse (ISO 4.3) [DOC845, DOC842, DOC843, and DOC846]. The GDL has 3 designated staff responsible for ensuring document control [DOC1196]. They have specific areas of responsibility and report formally via Quality Management team meetings. Documents are regularly reviewed, updated and approved for use by authorised personnel prior to use [MP 000 135]. Version control is in place with only documents used from an active register. Obsolete documents are retained. Documents are organised in Q-Pulse depending on the nature of the document as shown below.

Trust documents can be accessed by all staff through the intranet. A separate document control process exists for documents relating to CMFT policies (Trust policy ON8-2524 Document Control Policy).

* 1. **Service agreements**

Each request for testing is considered an agreement with the service user. The requirements of the service user are indicated on the MCGM website ([www.mangen.org](http://www.mangen.org)) and specific instructions given on some referral forms export forms and handbooks [DOC1134].

Under certain circumstances specific contracts for medical laboratory services are put in place [DOC1192]. These service level agreement contracts are documented on Q-Pulse [Management & HR>Service Level Agreement (SLA)].

Any new services are designed, developed and validated appropriately [DOC2063]. GDL staff are appropriately trained (ISO 5.1.5) and deemed competent (ISO 5.16) in the skills and expertise necessary for examination processes.

* 1. **Examination by referral laboratories**
     1. **Selecting and evaluating referral laboratories and consultants**

The GDL periodically sends samples to external laboratories, mainly for Molecular Genetics or Biochemical Genetics tests not available at the GDL. Samples are exported on behalf of external and internal (Clinical Genetics) referrers. Lists of referral laboratories and their repertoire are maintained [DOC2166, QF 000 006]. This standard (ISO 4.5.1) is met by the laboratory document on 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 periodic monitoring of referral laboratories is documented [DOC3082, QF 000 006].

* + 1. **Provision of examination results**

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). Molecular Genetics reports are sent direct to the clinician and a copy requested to be sent to the GDL for reference (export letter).

* 1. **External services and supplies**

The GDL has 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]. A list of approved suppliers to the GDL can be found on Q-Pulse Suppliers Module and is periodically reviewed. The GDL records any problems with equipment as nonconformities in the Asset register and any problems with reagents, consumables and services as GDL nonconformities.

* 1. **Advisory services**

The MCGM website offers general information on the use of services, sample types and requirements ([www.mangen.org](http://www.mangen.org)). It also provides the means by which the GDL can be contacted for further advice. The laboratory procedures for reporting results (ISO 5.8 & 5.9) ensure that appropriate clinical advice and interpretation is included in the written report. Further clinical advice and report interpretation can be communicated by telephone. Clinical advice and interpretation is only given by appropriately trained scientific staff. It is available during routine working hours, Monday – Friday (with the exception of Bank Holidays, Christmas Day and Boxing Day).

* 1. **Resolution of complaints**

The GDL has a system by which complaints are recorded on Q-Pulse, processed and monitored until resolved (ISO 4.8). User feedback is also recorded on Q-Pulse. Any user suggestions through feedback from user survey or personal communication are considered. User surveys provide a means to assess the clinical relevance of all genetic investigations performed within the GDL and the reliability of interpretive reports in conjunction with users. The document DOC1187 meets this standard. The GDL participates in the evaluation of clinical effectiveness, audit and risk management activities within CMFT via the Directorate Clinical Effectiveness Group.

* 1. **Identification and control of nonconformities**

Procedures are in place to ensure that nonconformities are managed effectively (ISO 4.9). The Quality Management team via the quality leads are responsible for managing nonconformities [DOC1508]. They ensure that actions are appropriately assigned and completed within an established timeframe. The document DOC1006 describes how the GDL meets this standard.

* 1. **Corrective action**

All nonconformities originating in the GDL are investigated and appropriate corrective actions implemented (ISO 4.10). Corrective actions are identified through errors and incidents, complaints and audit nonconformities and managed via the Q-Pulse non-conformance module [DOC1006]. The root cause is determined for any nonconformity and procedures are in place for when a full root cause analysis is required [DOC1008].

As part of continual improvement, all GDL nonconformities are reviewed 3-6 months following reporting to ensure that all corrective actions have been completed and to check for further instances of the nonconformity and error trends.

* 1. **Preventive action**

Preventive actions are identified through audit nonconformities, staff and user suggestions, survey feedback and external quality control scheme feedback and managed via the Q-Pulse non-conformance module [DOC1006]. Preventive actions are implemented where appropriate (ISO 4.11) and the root cause of potential nonconformities determined.

* 1. **Continual improvement**

Quality improvement is an essential role for all staff at all levels of the service to ensure the GDL delivers a high quality service (ISO 4.12). Improvement suggestions and ideas are welcomed and encouraged from all. Quality improvement can be proactive – new ideas about different ways of working, achieving increased efficiency for example. Quality improvement can also be reactive as results of scheduled internal audits, review of adverse incidents (reported to the Trust), incident reports (reported on Q-Pulse), user feedback/complaints as well as external quality assessment (accreditation and EQA schemes). Improvement suggestions are discussed and developed in team meetings (including the quality team) and include discussion of remedial action, corrective action, preventative action, root cause analyses and improvement processes. Continued quality improvement monitoring includes scheduling of audits (new audits as a result of non-conformance or repeat audits to monitor for improvement) and a 3-6 month review of non-conformances. Staff suggestions for improvement can be recorded via the Q-Pulse database. The results of the quality improvement programme form a part of the development, training and education of all staff. Continual improvement is discussed and actioned in Quality Management Team meetings; minutes of which are documented, circulated to participating staff and available to all staff via Q-Pulse. The GDL Quality Objectives are also available to all staff [DOC1343]. Analysis of the data collected forms part of the annual review (also distributed to all staff via Q-Pulse; ISO 4.15).

* 1. **Control of records**

The GDL has procedures to meet the requirements for controlling process records and quality records (ISO 4.13). The details of all documents, their storage and retention are documented [DOC1279 and DOC846]. The laboratory complies with current legislation, regulations and guidelines determining the timescales for storage of such records (NHS & RCPath). Obsolete examination process records are available on Q-Pulse to reconstruct the process of any examination.

* 1. **Evaluation and audits**
     1. **General**

The GDL has established a procedure for evaluations and audits including pre-examination, examination and post-examination procedures and the quality management system (ISO 4.14.1) [DOC1288]. The record of internal audit includes the activities, audited areas or items, any nonconformity or deficiencies found, with recommendations and time scales for corrective and preventative action. Full details of evaluations, the audit schedule and completed audits are recorded via Q-Pulse. The results of internal audit are regularly evaluated and the decisions taken documented monitored, reviewed and acted upon by the Quality Management Team in order to continually improve the effectiveness of the quality management system. Internal audits and evaluations are discussed in the annual management review.

* + 1. **Periodic review of requests, and suitability of procedures and sample requirements**

The senior management periodically review the examinations provided by the GDL. There is also periodic audit of the quality, packaging and transport of samples to the GDL (ISO 4.14.2).

* + 1. **Assessment of user feedback**

The assessment of user feedback is done through user feedback, complaints and via the use of satisfaction questionnaires (ISO 4.14.3) [DOC1187]. All user complaints and feedback are recorded in the non-conformance module of Q-Pulse. The results of user satisfaction surveys are now recorded on Q-Pulse within the audit module (2015 onwards). This ensures that all feedback is recorded and reviewed and any appropriate actions taken.

* + 1. **Staff suggestions**

There is an informal staff suggestions whiteboard as well as a module on Q-Pulse where suggestions can be raised. These are evaluated by senior members of staff, implemented as appropriate and the outcome communicated to the individual making the suggestion.

* + 1. **Internal audit**

Audits are conducted against agreed criteria including the relevant ISO 15189:2012 standards. The internal audit of pre-examination, examination and post-examination processes is planned and scheduled on a yearly basis through the Audit Module of the Q-Pulse database. Examination, Vertical and Horizontal audits are conducted following the laboratory policy and procedures available on the Q-Pulse database [DOC1288, DOC1509, MP000 043]. The results of all internal audits are evaluated by the Audit Lead and/or Quality Manager who ensure that corrective and preventative actions are undertaken in a timely fashion and communicated to all members of staff via Laboratory meetings and e-mail. All details of the audit, an audit check list (if appropriate), nonconformities, and the corrective and preventative actions are recorded on Q-Pulse. A significant number of staff members are appropriately trained in the procedure of internal audit [QF 000 002].

* + 1. **Risk management**

The GDL records non-conformances relating to problems with examination procedures and appropriate actions are undertaken (points 4.10-4.12). There are Trust procedures for reporting of non-conformances and for recording risk [Trust policy ON6-2802]. These use a web-based risk register (Ulysses) to document and escalate risk. The Trust requires the completion of a general risk assessment for the laboratory [DOC2931]. The GDL also carries out risk assessments for equipment and laboratory processes [DOC466, DOC2039].

* + 1. **Quality indicators**

Key quality indicators are recorded and monitored [DOC1017]. These include mandatory annual appraisal and training conformance, completion of document/audit/non-conformance activities, error trend analysis, staff/user suggestions/complaints, and EQA. Quality indicators are reviewed in the Quality Management Team meeting. There are some requirements to provide national data [DOC2153].

* + 1. **Reviews by external organisations**

The GDL is accredited by external assessment and is currently CPA (UK) accredited under 2 reference numbers – the Willink Biochemical Genetics laboratory as 2766 [DOC2252, DOC829, DOC1276] and the joint Cytogenetics and Molecular Genetics laboratory as 4015 [EO 000 044, DOC2810, DOC1276]. External accreditation assessment is recorded as an audit on Q-Pulse and all assessment findings recorded as non-conformances.

* 1. **Management review**

The Quality Team and Management representatives produce an annual management review (AMR; ISO 4.15) [DOC1020]. The Quality Manager, Senior Managers and Trust Directorate representatives participate in an AMR meeting. The AMR includes the following items of information:

1. A report from the GDL Director
2. Reports from key laboratory sections with reference to major changes in organisation and management, resources (including staffing) and processes
3. Report from the Quality Team including a review of laboratory performance for the year against key performance indicators (ISO 4.14.7) and a review of annual objectives (ISO 4.1.2.4)
4. A review of the quality policy (ISO 4.1.2.3)
5. Assessment of user feedback/complaints (ISO 4.14.3) and staff suggestions (ISO 4.14.4)
6. Review of internal audit (ISO 4.14.5)
7. Review of risk management (ISO 4.14.6)
8. Review of accreditation by external organisations (ISO 4.14.8) and of external quality assessment (ISO 5.6.3) [QF 000 004, DOC3090] CEQAS[[1]](#footnote-1), UKNEQAS[[2]](#footnote-2), EMQN[[3]](#footnote-3), CFEN[[4]](#footnote-4), ERNDIM[[5]](#footnote-5) and CDC[[6]](#footnote-6).
9. The status of preventive, corrective and improvement actions (ISO 4.9) and continual improvement
10. Review of the minutes and matters arising from the previous annual management review.

Records are kept and key objectives for subsequent years defined and plans formulated for their implementation. Both the AMR and AMR meeting minutes are available to all members of staff on Q-Pulse [DOC1020].

1. **TECHNICAL REQUIREMENTS**
   1. **Personnel**
      1. **General**

Procedures exist for the following areas of personnel management (ISO 5.1.1) and are available to all members of staff either through the host organisation (via the Trust intranet site <http://intranet.cmht.nwest.nhs.uk/policies>) or within the GDL via the Q-Pulse database as appropriate. Personnel organisation is shown in figure 3.

* + 1. **Personnel qualifications**

All staff members are suitably qualified to take up their position at the GDL with appropriate education, training, experience and skill. Documented evidence of staff qualifications is stored in staff personnel files. All staff employed as Clinical Scientist grades are HCPC state registered. Trained Genetic Technologists are directed towards the voluntary state registration register. Staff recruitment takes place via the Trust Recruitment office and their procedures.

* + 1. **Job descriptions**

Each member of staff has a job description and contract of employment with CMFT. These are in compliance with current legislation and provide clear terms and conditions of service. Staffing includes individuals with specific roles such as technical management, quality management, training and education, and health and safety [DOC2072].

* + 1. **Personnel introduction to the organisation**

All new staff members are required to undertake induction (ISO 5.1.4). All new staff members attend an induction programme provided by the Trust on their first day of employment. Additionally they undertake a specific induction to the laboratory [DOC772, DOC775, DOC968, DOC2854, MF 000 062]. Induction and mandatory training specific to the section and position in which they will be working is also given using the appropriate documents (logbooks) which are available in the Q-Pulse document register. A record of the areas of induction undertaken is kept in the personal records of each member of staff.

* + 1. **Training**

Appropriate training is provided for all staff which includes training of specific work processes, health and safety requirements, quality management system, information management system, ethics and confidentiality [E&T000 019]. Training and education needs for all trained staff (ISO 5.1.5) are identified through annual appraisal (ISO 5.1.7). Once trained and deemed competent, all individual staff have responsibility for the output and quality of their own work.

The GDL has a Training Officer to develop policies and procedures, provide an oversight of training needs, to organise training within the laboratory. The current post holder is Mrs Heather Ward. There are regular GDL and Genetic Medicine seminars with internal and external speakers presenting diagnostic, research, journal article appraisal and technical workshops. All staff are invited to attend.

* + 1. **Competence assessment**

Once trained, all staff members are assessed by various means to ensure competency [DOC840]. This can be facilitated by direct observation, verbal assessment, review of training, assessment of EQA scheme performance, and assessment of problem solving skill.

* + 1. **Reviews of staff performance**

Each member of staff has an annual appraisal with their line manager to ensure continued competency, review staff performance (ISO 5.1.7), set individual objectives and identify learning needs. This uses the Trust appraisal documentation and guidance which is available on the Trust intranet (<http://odt.staffnet.cmft.nhs.uk/appraisal.aspx>). The Trust provides training for all staff undergoing review and those conducting the review. The appraisal process includes the review of Trust/departmental/team objectives, job description, personal objectives and development plan, and training and development needs. A copy of the completed appraisal documentation, which includes an agreed personal development plan, is placed in the staff member’s personal file. The Trust maintains a record of appraisal dates for all staff and monitors compliance.

* + 1. **Continuing education and professional development**

Learning needs are identified at annual appraisal. There are Trust education courses as part of organisational development and training (<http://odt.staffnet.cmft.nhs.uk/>), laboratory seminars and other opportunities available for staff to enable continued education and professional development.

* + 1. **Personnel records**

Each member of staff has a personal file kept by the Director of the GDL to which they are entitled to see on request (ISO 5.1.9). The files contain:

1. personal details
2. employment details
3. job description
4. terms and conditions of employment
5. a record of staff induction and orientation
6. relevant education and professional qualifications
7. record/certificate of registration, if relevant/not available elsewhere
8. record of return to work following absence
9. accident record
10. a record of annual appraisal and personal development plan
11. record of disciplinary action [Trust policies, ON11-4388, ON3-2518, ON3-2583]
12. record of competency (held on Q-Pulse and/or in paper format by staff)
13. a record of attendance at fire lectures (held by the Trust)

An occupational health record is held by the Occupational Health Department within the Trust. Each member of staff has a Training & Development Portfolio which they are required to keep up to date with information and data relating to their personal professional development (courses and scientific conferences attended) which can also be held on the Q-Pulse. Clinical Scientists hold a CPD Training Record and/or are registered for the Royal College of Pathologists CPD Scheme.

* 1. **Accommodation and environmental conditions**
     1. **General**

The Manchester Centre for Genomic Medicine occupies the 6th floor of the CMFT major hospital building. It is designated as part of St Mary’s Hospital [DOC24]. Access to the department is restricted via swipe cards.

Specimens are delivered to the Manchester Centre for Genomic Medicine Mail Room (samples for all laboratories) or via a pneumatic pod system to the pre-analytical laboratory (samples for Molecular Genetics and/or Cytogenetics tests) [DOC1329, DOC1330].

* + 1. **Laboratory and office facilities**

Access to the GDL is restricted which ensures safety, quality and confidentiality. Suitable facilities (space, equipment, consumables, safety equipment (PPE), computer facilities, and environmental conditions including lighting, water and waste disposal) are provided for staff to allow for the correct performance of all examinations [DOC473].

* + 1. **Storage facilities**

Facilities exist within the laboratory for storage of materials in accordance with national legislation (ISO 5.2.3), including process and quality records [DOC1279], clinical material [DOC1464], hazardous substances [DOC2022], reagents [DOC2025] and waste material for disposal [DOC2064].

* + 1. **Staff facilities**

Suitable facilities are provided for staff welfare including secure locker space, sufficient toilet and shower facilities, basic catering facilities with a staff room and access to the hospital cafeteria, cafes and shops [DOC473].

* + 1. **Patient sample collection facilities**

The GDL does not offer facilities for patient sample collection.

* + 1. **Facility maintenance and environmental conditions**

The Trust holds a contract with Sodexo to provide building and environment maintenance, cleaning, and some equipment maintenance and service. Curatorship and stock control ensures that laboratory areas and equipment are clean and operational [DOC2031, MF 000 041, H&S000 006, DOC2108]. Temperature monitoring is in place in critical areas such as freezers and refrigerators [DOC638]. Pre- and post- analytical laboratories and office areas are clearly separated. Cell culture laboratory areas are clearly defined.

* + 1. **Health and Safety**

The GDL provides a safe working environment for staff in accordance with current legislation [DOC2021, Trust ON2-2604]. The Manchester Centre for Genomic Medicine has a Health and Safety Officer, Ed McHale. Each laboratory within the GDL has an appointed Health and Safety Lead who works with the Health and Safety Committee to ensure that all areas of this standard are met.

All staff are given information about the Health and Safety procedures within the laboratory during their induction [DOC2854, MF 000 062, DOC504]. Any issues relating to Health and Safety are discussed in Quality Team Meetings and in regular team meetings. Model rules exist for visitors to the department [DOC1420] outlining relevant Health and Safety matters.

All laboratory procedure documents include any relevant risk assessments [DOC2931, DOC2039]. CoSHH documentation (individual assessment checklist forms) is available on Q-Pulse for chemicals used in the GDL [DOC2014, DOC2325, DOC1524].

* 1. **Laboratory equipment, reagents, and consumables**
     1. **Equipment**

The GDL has equipment which is sufficient and appropriate to provide the laboratory service (ISO 5.3.1). There is a document that details the policy and procedures for the selection, procurement, purchase, management and maintenance of equipment [DOC2107]. Equipment is validated or verified before use [DOC3125]. Individual protocols detail with the correct day-to-day use and maintenance of equipment; these are drawn up in line with manufacturer’s recommendations. Equipment is operated only by trained staff.

Information about equipment suppliers, a record of laboratory assets (equipment) and any records of equipment service, maintenance and calibration (as appropriate) are stored in the Equipment and Assets module of the Q-Pulse database. The Q-Pulse Equipment and Assets module also has the facility to record equipment breakdowns. 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. Adverse incidents involving equipment are reported via the non-conformance module on Q-Pulse and if appropriate the equipment is placed on the risk register. Items of equipment are either serviced, repaired or calibrated by Sodexo or are contracted to external sources following decontamination [LP 000 240].

Where appropriate, equipment is calibrated for use according to manufacturer’s recommendations by external contractors and if use of the equipment affects the examination result calibration is carried out to ISO standards [DOC3172]. All calibrations are recorded in the equipment record on Q-Pulse. There is no point-of-care testing carried out within the GDL.

* + 1. **Reagents and consumables**

The GDL operates a system for the management [DOC3386, DOC2025] and regular monitoring of stock of reagents and consumables to ensure sufficient supply is available to maintain the service (ISO 5.3.2) [DOC2108]. Stock levels are replaced based on both usage and the likely time taken for replacement orders to be delivered to prevent deterioration [DOC2106]. Acceptance testing is carried out as appropriate [DOC3387]. A list of all chemicals is available including identity, manufacturer details, COSHH Q-Pulse number, and acceptance for use [[COSHH Project](file:///\\cmftgen5\Genetics_Shared\COSHH%20Project\CoSHH%20Project%20Tracking%20-%20USE%20THIS.xls)]. All procedures are risk assessed before any processing begins and this includes evaluation of any new chemicals assessed for their COSHH regulations prior to any order being placed. Suppliers are evaluated as part of the procurement process. The Health and Safety Officer will advise on whether waste chemicals can be disposed of safely using means available to the laboratory or whether specialist removal is required [DOC2064]. Adverse incidents involving reagents, consumables or suppliers are reported via the non-conformance module on Q-Pulse. Audit trails of all kits, reagents and working solutions are retained.

* 1. **Pre-examination processes**
     1. **General**

Documented procedures are in place for all pre-examination processes.

* + 1. **Information for patients and users**

Information for patients and users (ISO 5.4.2) is available via the MCGM website ([www.mangen.org](http://www.mangen.org)) and a Q-Pulse record ensures document control [DOC188, DOC2192]. Information held on the website includes the location, contact details and business hours for the GDL, types of tests offered (including turnaround times) and sample requirements (container type, quantity, transport, acceptance policy). Price lists are available on request [DOC2017, DOC2157, DOC2289, MP000 021].

* + 1. **Request form information**

Requests for the majority of examinations (ISO 5.4.3) are made using an appropriate referral form [DOC19, LF160 001, DOC512, LF 000 149]. Information is provided to enable their completion. Specific forms are required for stratified medicine services [LF 000 207, LF 000 208], the 100,000 Genome project [DOC2839, DOC2840, DOC2895], exports [LF 000 141, DOC979] and for other specific requests.

Request forms are available directly from the website ([www.mangen.org](http://www.mangen.org)) and are version controlled via Q-Pulse. The following information is requested from the user:

* the necessary information required for unique and unequivocal patient identification (can include name, date of birth, NHS or hospital number, gender)
* date specimen taken (and time, but only if appropriate to the test)
* type of specimen
* clinical reason for the request and investigation requested as well as clinical details that may influence the examination performance and/or interpretation of results
* full consultant and referring centre details
* urgency of the test
* other information when appropriately required (consent, high infection risk, gestation and date of delivery).

Space is available on the referral form for the laboratory to include a unique laboratory accession number, the date of arrival in the laboratory, indication of priority status, and any pre-examination processes required (depending on the specimen). The date of arrival of a sample request in the laboratory is recorded automatically in the relevant laboratory information management system.

Users are encouraged to complete the request forms fully. Incomplete information is requested where necessary by telephone (urgent cases) or letter. Where there is a verbal request for testing, confirmation in writing is required (email, fax 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**

Information concerning specimen collection and handling (ISO 5.4.4) is available on the reverse of referral forms or via the website ([www.mangen.org.uk](http://www.mangen.org.uk)). The laboratory is not directly involved in specimen collection for any of its sample types. Informed consent is inferred by a written request for testing (usually as a referral form) from a clinician.

* + 1. **Sample transportation**

The MCGM website ([www.mangen.org.uk](http://www.mangen.org.uk)) contains model rules and detailed information for the packaging and transportation of specimens to the GDL to ensure specimens arrive safely with the integrity of the sample maintained (ISO 5.4.5) [EO 000 033, DOC1419].

* + 1. **Sample reception**

Specimens for GDL are received and handled appropriately (ISO 5.4.6) [LP000 019, DOC469, LP160 005]. Specimens are delivered to the 6th floor mail room close to the Lift and Stairs in Core Lift Junction 8 in the Royal Manchester Children’s Hospital (L.6.CV.220). Samples for Molecular Genetic or Cytogenetic tests are transferred prior to unpacking to the Specimen Reception in the Pre-analytical laboratory. Alternatively, samples are received via the pneumatic pod system to the reception point or pre-analytical laboratory. Samples for Biochemical tests are transferred prior to unpacking to the Willink specimen reception area [DOC641, DOC614, DOC1041]. Sample referrals are date and time stamped at receipt and the urgent samples dealt with promptly.

The specimen and referral form are checked for quality and continuity and are rejected if the specimen is suboptimal or when specimen and form are not sufficiently linked [DOC1563, LP000 026].

Leaking samples and high risk samples are treated appropriately [DOC1417, DOC2044]. Suitably qualified Duty Scientist staff ensure that samples are appropriate for testing [LP000 029, DOC641, DOC614]. Any sample transfers are checked and transfer containers labelled appropriately to ensure traceability to the original primary sample.

* + 1. **Pre-examination handling, preparation and storage**

GDL samples are stored appropriately prior to preparation and testing [DOC1464, DOC1459].

Procedures are in place to ensure the continued suitability of samples for testing including time limits for requesting additional tests on a stored primary sample [DOC1464].

* 1. **Examination processes**
     1. **Selection, verification and validation of examination procedures**

All new examination procedures are verified or validated prior to introduction (ISO 5.5.1) [DOC2063]. 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. Performance characteristics can include measurement trueness, accuracy and precision (repeatability and intermediate precision), measurement uncertainty, analytical specificity/sensitivity, interfering substances, limits, measuring interval, and diagnostic specificity/sensitivity. Measurement uncertainty is determined to ensure robustness of quantitative values output for patient results.

Copies of validation information are kept on Q-Pulse or a GDL shared network and some paper copies. Any significant changes to examination procedures are revalidated and reported to relevant users prior to implementation. Users are asked for their views regarding examination procedures via user surveys (ISO 4.15).

* + 1. **Biological reference intervals or clinical decision values**

For quantitative (and some 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 regularly.

* + 1. **Documentation of examination procedures**

Procedures are available for the conduct of all examinations within the GDL and are located on the Q-Pulse database in the relevant diagnostic section of the document register and are available to all staff. These procedures are reviewed regularly by examination and vertical audit and changed in the light of objectives and new methods as appropriate.

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 quality of examination results**
     1. **General**

Clinical Scientists and senior technologists ensure that the appropriate processes are developed, validated and implemented by all staff. Staff members are trained in the use of documented procedures. Procedures are available for the use and acceptance of internal quality control systems for all genetic laboratory examinations for which such control systems are required [DOC1564].

* + 1. **Quality control**

Laboratory tests are IQC risk assessed [QP 000 003, MP 000 085]. IQC measurements and results are recorded, regularly evaluated and any subsequent corrective and/or preventive actions recorded.

Examination procedures use internal assay standards, reference materials, assay controls, positive/negative controls and blanks, as appropriate, to ensure quality of patient results. Internal quality control measures are indicated in individual examination procedures. 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.

* + 1. **Interlaboratory comparisons**

The GDL has a procedure for the participation in interlaboratory comparisons and the evaluation of performance (ISO 5.6.3) [DOC1564, DOC697]. The GDL participates in External Quality Assessment Schemes organised by CEQAS, Molecular UKNEQAS, EMQN, ECFN, ERNDIM and CDC (ISO 4.14.8). Where there are no specific schemes available the GDL will participate in generic technical schemes or exchange of samples with other laboratories. A record of performance is kept in several locations (electronically stored on Q-Pulse [QF 000 004, DOC2062], on the Genetics servers and within the GDL secure account areas and on the EQA scheme organiser websites). EQA activity is communicated to all staff at laboratory meetings (see 4.1.2.6) and via the Quality Notice boards in Rooms L6.CV.062, L6.CV.107 and L6.CV.290. Point deductions and poor performance are recorded as non-conformances in Q-Pulse and are appropriately investigated. The summary of EQA performance allows for trend analysis.

* + 1. **Comparability of examination results**

All examination procedures are carried out on a single site and individual tests generally use the same samples, equipment and methods for all patients. Where differences exist, these variations are incorporated into test validation.

* 1. **Post-examination processes**
     1. **Review of results**

All analytical data (including duplicate or confirmatory testing) is analysed independently by two appropriately trained staff members, the second being a registered clinical scientist. Internal quality measurements are reviewed as appropriate. Concordance of analytical data ensures accurate results. All examination results are authorised before release by appropriately trained staff [MP000 004, DOC2077].

* + 1. **Storage, retention and disposal of clinical samples**

The GDL has procedures to meet the requirements for the control of clinical material (ISO 5.7.2). There is a GDL procedure for the storage, retention and disposal of biological materials [DOC1464] which conforms to the recommendations of the Royal College of Pathologists [MP000 057]. Other documentation refers to procedures for leaking samples [DOC1417], high risk samples [DOC2044], solid tissues samples in line with HTA recommendations [DOC2367] and for the return of tissue block samples [LP 000 142].

* 1. **Reporting of results**

The GDL has defined reporting procedures for the reporting of results (ISO 5.8) [DOC2066, MP 000 014, DOC463]. Laboratory reports are currently created through 3 separate LIMS with reports through each following a specific electronic format. They are produced using either (i) the Molecular Genetics laboratory database or (ii) the Shire Management database (Cytogenetics tests) or (iii) APEX (Biochemical Genetics tests). A single LIMS is being developed for the reporting of both Cytogenetic and Molecular Genetics results (iGene, Genial Genetics).

The GDL aims to achieve national guidelines for the reporting time for all examinations, where such guidelines exist. Where applicable the laboratory turnaround times reflect the clinical needs of the user. Turnaround times are monitored and reviewed at laboratory team and quality meetings and action plans introduced if reporting times are not being met. Target turnaround times are published on the website ([www.mangen.org.uk](http://www.mangen.org.uk)). Cytogenetics and Molecular Genetics reporting times are collected and reported quarterly via the Trust Audit department for specialised services quality dashboards [DOC2153].

Reports are clear, unambiguous and conform to requirements of professional best practice and the requirement of approved standards (ISO 5.8.3). Reports include the following information:

* Identification of the test or examination and measurement procedure (where appropriate)
* Identification of the GDL including contact details
* Name and contact details of the service user and any other referrer to whom a copy of the report is to be sent
* Date of sample collection/receipt and date of report
* Clear reporting of examination results using appropriate nomenclature and/or units
* Reference intervals, clinical decision values or comparison to control values if appropriate
* Interpretation of the results
* Cautionary comments or explanatory notes
* Whether the test is part of a research programme or if not an accredited test (following ISO accreditation)

When required, reports will include comments regarding:

* Test specifications and limitations
* Sample quality which may/has compromised the quality of results
* Sample suitability, particularly with respect to rejected sample
* Critical results and reference ranges
* Whether tests have been repeated or confirmed using an alternative methodology

Such comments can form part of the report template or as report ‘notes’ added when specifically required.

* 1. **Release of results**

There are strict criteria regarding who can release results and to whom (ISO 5.9) [DOC2065]. Reports are released to service users by post, telephone fax or email depending on the examination type [DOC2065]. Policies [DOC2805, DOC2806, MP 000 101] are in place to ensure that reports are handled and transmitted confidentially. There is an approved system for the automated selection and reporting of results for Biochemical Genetics tests through NPEX. All reports are authorised prior to release. Occasionally amended reports are issued to the service user following defined criteria (ISO 5.9) [DOC2048].

* 1. **Laboratory information management**
     1. **General**

The GDL utilises a number of laboratory data management systems and software applications which generate a large amount of data. The policies and procedures are documented [DOC3115]. Data is stored on allocated CMFT server space. There are procedures in place which conform to accreditations standards (ISO 5.10) to ensure the security, access, confidentiality [DOC2051] and data protection [Trust ON4-2498, ON3-2601], back-up of data, and the storage, archive and retrieval of data [DOC3115]. All PCs in the Trust are password protected and all staff member have their own log in password. Other software applications are also password protected to ensure patient security. Access to electronic patient information (LIMS) is restricted and separate security levels set for enabling patient data entry, general access to data, changing or acceptance of examination results, reporting results and authorising reports.

* + 1. **Authorities and responsibilities**

Staff members are allocated defined levels of access to LIMS as appropriate to their laboratory role and grade. Staff members may be permitted to access LIMS and enter patient data and information, where others are permitted to change or report patient data or examination results or permitted to authorise and release results and reports.

* + 1. **Information system management**

Laboratory data management systems and software applications used for the collection, processing, recording, reporting, storage and retrieval of examination data are appropriately verified or validated for use including ensuring information is accurately reproduced. Documented procedures are available for the day-to-day use of GDL LIMS systems [DOC3049, LP 000 107, DOC1499, DOC3225]. Staff members are appropriately trained in their use. Systems are password protected and safeguarded against unauthorised access, breach of confidentiality and tampering or loss of information. All non-conformances associated with data systems and software are recorded on Q-Pulse and investigated appropriately.

There are documented contingency plans in place to ensure continuing service provision to service users [DOC2809].

1. **Appendix**

A summary GDL documents on Q-Pulse can be found by clicking on the link below.



1. Cytogenetic External Quality Assessment Service [↑](#footnote-ref-1)
2. United Kingdom National External Quality Assessment Schemes for Molecular Genetics [↑](#footnote-ref-2)
3. European Molecular Genetics Quality Network [↑](#footnote-ref-3)
4. Cystic Fibrosis European Network [↑](#footnote-ref-4)
5. European Research Network for evaluation and improvement of screening, Diagnosis, and treatment of Inherited disorders of Metabolism [↑](#footnote-ref-5)
6. Centres for Disease Control [↑](#footnote-ref-6)