# Title: Quality Manual – Pathology Departments

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Mark relevant procedures/policies

| DSE | Lifting/ Handling | COSHH | Spillage | Disposal | Sharps | Risk Assessment | MSDS |
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The below risk/safety assessments must be read and understood before carrying out this procedure. Details are recorded in the main text of the document.

RELEVANT SAFETY DATA, COSHH AND RISK ASSESSMENTS:

## 1. GENERAL INFORMATION

This document together with the Quality Policy and specified standard operating procedures (available on QPulse – Gael Quality), and other documents represents the Quality Management System of the Pathology Departments of County Durham and Darlington NHS Foundation Trust (CDDFT). It has been compiled to meet the requirements of the ISO 151589 *Medical laboratories – Requirements for quality and competence and accreditation,* accredited through United Kingdom Accreditation Service (UKAS), and other appropriate National and International standards and licensing bodies. All processes and procedures specified herein are mandatory within the Departments of Pathology. This manual contains generic information for the Pathology Departments as a whole. Information regarding the distribution and review history of this document can be found in the document control system.

**Scope and purpose of this document**
This procedure describes the quality manual for the Departments of Pathology. Throughout the text there may be references to ISO Standards, laboratory procedures and Trust documentation written in fulfilment of these standards.

This Quality Manual can be regarded as the index volume to separate volumes of management, laboratory, clinical and quality procedures that constitute the quality management system.

The sections of this Quality Manual are arranged so that they equate with the format of the Management and Technical requirements of ISO 15189. Under the title of each ISO 15189 sub clause, there is a brief description of the way in which the Pathology Service seeks to comply with the particular sub clause; references are given to appropriate Trust and Pathology Procedures.

**Normative Reference and related documents**
The following referenced documents are necessary for the application of this document. For dated references only the edition cited applies, for undated references, the latest edition of the referenced document applies.

- ISO/IEC 15189:2012(E) Medical Laboratories – Requirements for quality and competence.
- UKAS Publications including Publications Relating to Laboratory Accreditation (ISO 15189) and Technical Policy Statements (from the publications site on UKAS website)
- Blood Safety and quality regulations (2005) No 2898 available at http://www.legislation.gov.uk/uksi/2005/2898/contents/made
- Blood Safety and quality (amendment) (No 2) regulations (2005) No 50 available at http://www.legislation.gov.uk/uksi/2005/50/contents/made
- Blood Safety and quality (amendment) regulations (2006) No 2013 available at http://www.legislation.gov.uk/uksi/2006/2013/contents/made
- Human Tissue Authority https://www.hta.gov.uk/codes-practice

- Medicines and Healthcare Regulatory Agency https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency]
- NHS SLA template https://www.england.nhs.uk/wp-content/uploads/2016/04/1-nhs-full-length-1617-parts-apr16.docx
- RCPath GO31 Royal College of Pathologists guidelines on the Retention and Storage of Pathological Records and Archives 5th edition 2015 https://www.rcpath.org/resourceLibrary/the-retention-and-storage-of-pathological-records-and-specimens--5th-edition-.html

**Responsibility**

The Quality Assurance Manager is responsible for ensuring the implementation and maintenance of the quality procedures outlined, working with the Pathology Management Team, Clinical Staff and Laboratory staff and administration team.

All staff have responsibility to ensure quality of their own and any delegated practices through compliance with this and other documented policies and procedures. Staff are responsible for the quality of the tasks they perform and service they provide. They must be familiar with this manual and are encouraged to engage in improving this manual.

The Laboratory Management have overall responsibility for the Pathology Departments. The Laboratory Director has ultimate responsibility for the overall operation and administration of the laboratory. The Quality Manager supports the Senior Management of the Pathology Service to ensure compliance with this document.

**Terms and definitions**
Please see *Appendix I* of this document for Terms & Definitions

**Quality Policy**
The Quality Policy QP/PA/GP/001 *(ISO 15189:2012 4.1.2.3)* of the Pathology Departments is published as a separate controlled document to be displayed within the laboratory as identified on QPulse.

2. Laboratory General Information and Information Management Requirements

General Laboratory Information

A single Pathology service covers the Trust and there are main laboratories on the acute sites of Darlington (DMH) & Durham (UHND). There is also a small reception area and blood issue fridge at the non-acute sites at Bishop Auckland and Shotley Bridge Hospitals for receipt of samples prior to transport to the acute sites and for low risk patient blood transfusion.

The two main sites also provide services for primary care, with direct access requests from GPs accounting for approximately 50% of the workload of the service. The Pathology Directorate provides laboratory services to the County Durham & Darlington NHS Foundation Trust, Tees, Esk and Wear Valleys NHS Trust, H M Prison Service and General Practices throughout the Durham & Darlington area. The Pathology Departments, are divided between two acute hospital sites, the addresses are below:

| **Pathology Department** | **Pathology Department** |
|---|---|
| **University Hospital of North Durham (UHND)** | **Darlington Memorial Hospital (DMH)** |
| **North Road,** | **Hollyhurst Road** |
| **Durham** | **Darlington** |
| **DH1 5TW** | **DL3 6HX** |

## Pathology Services

The Pathology Departments provide a comprehensive laboratory diagnostic service encompassing the main disciplines of Clinical Biochemistry, Haematology including Blood Transfusion, Microbiology, Histopathology, Immunology and Cytology and Mortuary Service.

The Clinical Biochemistry, Haematology and Blood Transfusion and Microbiology offer a 24 hour laboratory service outside normal working hours. The service is Consultant led in each discipline. The departments currently have more than 200 staff, including consultants.

The Pathology Service is comprised of departments encompassing the 4 main disciplines:
Blood Sciences comprises Biochemistry, Immunology and Haematology.

- Biochemistry and Immunology provide a comprehensive laboratory service encompassing Automated Biochemistry, Endocrinology, Special Chemistry and Immunology encompassing autoimmunity, allergy and immunochemistry. Biochemistry offers a full 24 hour laboratory service. The service is Consultant led and 24 hour consultant advice is available.
- Haematology provides a comprehensive laboratory diagnostic service encompassing automated analysis, coagulation and transfusion sciences.

This directorate also offers a full 24 hour laboratory service. The service is Consultant led and 24 hour consultant advice is available.

- Microbiology provides a comprehensive laboratory diagnostic service encompassing bacteriology, mycology, serology and virology. The service is Consultant led and 24 hour consultant advice is available.
- Cellular Pathology provides a comprehensive laboratory diagnostic service encompassing histology, non-gynaecological cytology, and post mortem services. The mortuary operates a 24 hour on-call system across both sites. Andrology services are provided, but are a non-accredited service.

Full information on the range of services provided by all of the departments within Pathology, including opening times, contact information and test repertoire can be found on the:

- Trust internet site: http://www.cddft.nhs.uk,
- Pathology Handbook Pathology Handbook

Other discipline specific laboratory information can be found in the Electronic Pathology Handbook.

## 3. Organisation and Management Structure and Responsibilities ISO 4.1

### Organisation ISO 4.1.1

### General ISO 4.1.1.1

This Quality Manual describes how the Pathology Service meets the requirements of International Standard ISO15189:2012 when carrying out work at University Hospital of North Durham (UHND) and Darlington Memorial Hospital (DMH).

### Legal Entity ISO 4.1.1.2

The Department of Pathology is part of CDDFT which in its entity is legally responsible for its activities MF/PA/GP/EXT001 and meets the requirements of the standards and regulations stated in this document when carrying out work at any of its facilities.

### Ethical Conduct ISO 4.1.1.3

The Departments have arrangements in place for ethical conduct through the Trust management structure and Trust and local policies. (*ISO 15189:2012 4.1.1.1, 4.1.1.2*). All activities undertaken are free from undue commercial, financial or other pressures and influences that could adversely affect the quality of work produced. Should conflicting interests exist, Trust policy is that staff declare these in accordance with Trust policy

State registered scientists are subject to the Health and Care Professions Council code of conduct http://www.hcpc-uk.org/ and all staff treat human samples, tissues or remains according to relevant legal requirements as described in:

- LP/PA/HP/SOP50 Slide filing
- LP/PA/MOR/SOP5 Recording, return and sensitive disposal of PM material
- LP/PA/HP/SOP62 Storage, Retention and Disposal
- LP/PA/HP/SOP107 Specimen Disposal and Retention of Tissue after Cut Up
- LP/PA/CB/OP97 Biochemistry control of process and quality records and clinical material
- LP/PA/MB/GEN10 Procedures for the Control of Clinical Material
- LP/PA/HA128 Procedure for control of process and quality records and clinical material. Storage within Haematology and Transfusion

Confidentiality of information is maintained in accordance with Trust policy for Data Protection, Confidentiality and Disclosure and all staff complete an annual e-learning module on information governance as part of their mandatory training.

The Chief Executive of the Trust holds overall responsibility for the Trust including Quality and Governance and delegates through the management structure.

**Trust Services**
The Trust clinical services and support services are organised into Clinical Care Groups and Corporate Directorates.

**There are five Clinical Care Groups:**

- Integrated Medical Specialties (IMS)
- Community
- Surgery
- Family Health
- ***Clinical Specialist Service (CSS)***

**There are also Corporate Directorates:**

- Assurance, Risk an Compliance (ARC)
- Corporate Services
- CDD Services
- Finance
- Workforce and OD
- Medical Director
- Nursing and Service Transformation


Pathology sits within the Clinical Specialist Services Care Group. The diagram on the right outlines the management structure within the care group and the Speciality structures are available with the following documents:

**IT Staff Structure –** LF/PA/GP/IT001
**Blood Sciences** – LF/PA/GP/BSC002
Includes (Haematology, Transfusion, Biochemistry & Immunology)

**Cell Sciences as below:**

Cell Pathology Management Structure – LF/ND/CP/HR1
Histology Structure –LF/ND/CP/HR5
Mortuary Structure – LF/ND/CP/HR4
Microbiology Structure – LF/PA/MB/FORM1

**Laboratory Director ISO 4.1.1.4**

Pathology is directed by a Clinical Director who reports to the Medical Director and each discipline has a Clinical Lead. Pathology is managed by the General Pathology Manager who reports directly to the Associate Director of Operations for the care group.

The duties and responsibilities of the Laboratory Director are described in MF/PA/GP/DIR001 and include professional accountability for all aspects of the operation of the Pathology service

The professional Competence of the Laboratory Director is demonstrated in the following ways:

- By evidence of training and experience in a pathology specialty as normally exemplified, in the United Kingdom, by Fellowship of the Royal College of Pathologists or its equivalent.
- By evidence of continuing practice and experience in the specialty, with participation in continuing professional development.
- Having the confidence of the Centre Medical Director and the Chief Executive.

The Clinical Lead/Clinical Director for each area provides local professional and clinical direction on behalf of the Laboratory Director.

**Management Responsibility ISO 4.1.2**

**Management Commitment ISO 4.1.2.1**

Laboratory management is committed to the development, implementation and continual improvement of the QMS. This requirement is achieved by:

- Ensuring all laboratory personnel are aware of and comply with regulatory and accreditation requirements.
- Ensuring all laboratory personnel are aware of and comply with the needs and requirements of service users.
- Establishing and maintaining the Quality Policy.

- Ensuring quality objectives exist and plans to achieve these are in place.
- Defining the responsibilities, authorities and inter-relationships of all personnel. Establishing effective communication processes with staff and also with stakeholders.
- The appointment of a Quality Manager.
- Ensuring that quality reviews of all services occur on at least an annual basis.
- Ensuring staff are competent, and shown to be competent, to provide assurance they are able to perform their assigned duties.
- Ensuring there are adequate resources to enable the correct conduct of pre-examination, examination and post-examination activities.

**Needs of users ISO 4.1.2.2**

The needs of the users are kept under review. These are ascertained through regular contact and with user questionnaires. These are translated into requirements which form the focus of objective setting and planning within the quality management system. Assessment of user satisfaction and complaints is conducted on a regular basis and consideration of the findings form part of the annual management review.
Other measures include:

- Providing workload and quality measures to Trust and CCGs.
- Collaboration on Clinical Governance issues with local CCG clinical governance leads.
- Issue of user briefings.
- Involving hospital clinicians and G.P.'s as pilot sites for service developments such as testing protocols, interpretive reporting and electronic requesting and reporting links to Pathology.
- Provision of a detailed website containing user guidelines.
- User satisfaction activities.

**Quality Policy ISO 4.1.2.3**

The Quality Policy (QP/PA/GP001) describes the aims and objectives of the Quality Management System of the Division of Pathology and is outlined below:
The Pathology Service provides a diagnostic service comprising of Blood Sciences (Haematology, Blood Transfusion, Coagulation, Biochemistry and Immunology), Microbiology (Bacteriology, Virology, Serology) and Cellular Pathology and Mortuary services. Andrology services are provided, but as a non-accredited service.
The Pathology Service is committed to providing a service of the highest quality and shall be aware, of and take into consideration, the needs and requirements of its users.
The Pathology Service's aim is to ensure that the needs and requirements of users are met. The Pathology Service is committed to involving and developing staff so that they continuously improve work processes; introducing structured and systematic approach to management whilst establishing and maintaining a focus on meeting the needs of the stakeholders.

The Pathology Service aims to operate in accordance with standards and regulations set and/or assessed by UKAS (ISO15189:2012), MHRA, HTA and other relevant regulatory bodies.
Through this they will demonstrate a commitment to:

- Operate a quality management system to integrate the organisation procedures, processes and resources.
- Set and regularly review quality objectives and plans in order to implement this Quality Policy.
- Ensure that all personnel are familiar with the Quality Manual and all procedures relating to their work.
- Commit to the health, safety and welfare of its entire staff. Visitors to the department will be treated with respect. Due consideration will be given to their safety at all times whilst on the site.
- Uphold professional values and be committed to good professional practice and conduct.
- Ensure staff recruitment, training, development and retention at all levels.
- Ensure the proper procurement and maintenance of equipment and other resources as required for the provision of services.
- Periodically review requests, the suitability of procedures and sample requirements.
- Ensure commitment to the continuous improvement of all processes involved in the provision of the highest quality laboratory service, from the collection, transport and handling of laboratory specimens, through examination and the eventual reporting of timely, confidential, accurate and clinically useful results.
- Create a safe and secure working environment in the laboratory precincts.
- Ensure assessment of user satisfaction and the use of internal audit and external quality assessment in order to produce continual quality improvement.
- Commit to and comply with relevant environmental legislation.

The original Quality Policy is signed and dated by the Laboratory Director and Pathology Quality Manager.

**Quality objectives and planning ISO 4.1.2.4**

The Pathology Service management team defines the quality objectives of the laboratory in consultation with the individual departments and is responsible for ensuring that plans are made to meet these objectives. See MP/PA/GP/QO3 Quality Objectives Procedure and MP/PA/GP/QO4 Departmental Quality Objectives template. The Annual management review MP/PA/GP/AMR6 is undertaken on an annual basis and determines whether the objectives have been successfully completed. It provides an opportunity for revising such objectives and plans and the functioning of the quality management system.

The Pathology Service is committed to:

- Maintaining its performance in external quality assurance schemes, which includes dissemination of results and performance.
- On-going participation in internal and external audit.
- Continuing development of internal quality assurance measures, to minimise the risk to patients and staff.
- Providing and enabling staff training and development that ensures all members can deliver the service to the appropriate standard.

**Responsibility, authority and interrelationships ISO 4.1.2.5**

Pathology Services are provided by County Durham and Darlington Foundation Trust and have laboratory facilities at University Hospital North Durham and Darlington Memorial Hospital.

Pathology is divided into:

- **Blood Sciences** (*Clinical Biochemistry, Immunology and Haematology & Transfusion*)
- **Cellular Sciences** (*Microbiology, Cellular Pathology and Mortuary Services*)

**Clinical Director** (MF/PA/GP/DIR001) has overall responsibility for operation and administration of the laboratories and of providing leadership of the medical laboratory service, pathology financial management & budgets and pathology strategy. The Clinical Director has responsibility for professional, scientific, consultative / advisory, organisational, administrative and educational matters relevant to the services offered by Pathology as described in ISO 15189:2012 Clause 4.1.1.4a-o. The Clinical Director will delegate selected duties (Specialism specific) to the Clinical Lead for the departments and the Pathology Management Team and these will be documented within the QMS either via job descriptions or job plans. The Clinical Director and Pathology Management have responsibility for setting the strategic direction of Pathology taking into consideration all stakeholders and the Trust strategic direction. All staff including clinical staff will have duties, authorities and responsibilities documented either in a job description or job plan.

**General Manager** (MP/PA/GP/JD0014) who report to the Associate Director of Operations and they delegate to individual Service Managers one for each (Blood Science and Cellular Science). Service managers delegate to Laboratory Departmental Managers and other laboratory staff as per each discipline staff structure which is given as a related document to this manual

**Pathology Management** (MP/PA/GP/JD005 and MP/PA/GP/JD0017) has the responsibility for ensuring the Pathology Strategy is appropriately devised, communicated, delivered and reviewed and that operations are monitored and continually improved and that assurances are given to the Pathology Management and Trust Management on Quality & Governance issues.

**Quality Manager (MP/PG/GP/JD001)** has responsibility for ensuring the quality management system is implemented and maintained; reporting through the Governance Structure meetings and other management meetings on the functioning and effectiveness of the quality management system and co-ordinating awareness of the needs and requirements of users. A representative from each Department will act as the Quality Coordinator for that department and communicate with the Quality Manager to ensure the proper running of the Quality Management System.

**All staff** in Pathology have individual responsibility that they ensure they understand their own and others role in achieving quality outcomes and putting quality principles into practice.

Conversely, on occasion Pathology has a General Manager (Grade 8b) who reports to the Associate Director of Operations and they delegate to individual Service Managers (Grade 8a) one for each (Blood Science and Cellular Science). Service managers delegate to Laboratory Departmental Managers (Grade 8a) and other laboratory staff (Grades 2 - 7) as per each discipline staff structure which is given as a related document to this manual. The Quality Manager reports to the General Manager.

Conversely, on occasion staff will need to deputise for their line manager. In pathology, the Service Managers will deputise for the General Manager, and each other. The General Manager will provide support for either Service Manager in their absence, with some deputation being delegated to the relevant department managers. The Service Managers will engage support from the Associate Director triumvirate where necessary.

## Communication ISO 4.1.2.6

## Meetings and communications

As with other departments within the Trust, Pathology must have effective means of communication with its staff and stakeholders through communications systems (Information Technology, telephone and written communications) and meetings. All communications are recorded either in the form of minutes or other appropriate record (see Document Control and Records Management procedures). All meetings must have an approved and documented Terms of Reference which specifies the purpose, structure and required attendance of the meeting. The key meetings hosted by Pathology and featuring Quality Management and Clinical Governance are as described next.

- **The Division of Pathology Group – DOP** [*Terms of Reference **QF/PA/GP/TOR1***] meets once a Month with the remit to provide

assurance to Care Group and Executive Directors Group on progress and performance of Pathology and act as the strategic decision makers for the department.

- **The Directorate Health and Safety Committee** meets quarterly with the remit to review and provide assurance for all health & safety issues within Pathology.
- **Pathology Specialty Groups** meets as a minimum quarterly with the remit to review and provide assurance for departmental specialist clinical and operational issues and provide assurance to the DOP on progress and performance for the operational management issues of the departments including quality and governance.
- **Education and Development Group** meets as a minimum quarterly and reviews strategy and gives recommendations for any educational or development considerations within pathology.
- **Trust Transfusion Committee** meets as a minimum of quarterly and has a remit to review and give assurances for all Trust Transfusion issues.
- **Hospital Transfusion Team** (T3) meets monthly or more as required and has a remit to review and give assurances for Transfusion operational and governance issues.
- **Other meetings as required** the departments may incorporate other meetings into their schedule as required such as quality meetings, team meetings, senior meetings, joint laboratory meetings (Cell Sciences/Blood Sciences) etc.

Other Trust meetings will also require presence from Pathology Staff and may include the Care Group Risk Management Meeting, Trust Quality & Health Care Governance Meeting etc.
All information relevant to staff that is not of a confidential nature is placed on the staff notice boards and distributed to staff electronically via the Quality Management system ( QPulse).

Details of general courses and meetings are displayed on the departmental notice boards.

Departmental Health and Safety information is displayed on the Health and Safety notice boards.

All EQA results are placed in the EQA folders or notice boards in each section and remain until they are updated by new results.

Other sources of communication/information are:

- Trust Information via Trust Updates from Chief executive usually via the Trust Intranet. Also there is a monthly Trust Team Brief, which is discussed at each general laboratory meeting.

- Intranet – all staff will have access to the Trust intranet and the electronic document management system.
- E-mail – all staff have access to Microsoft Outlook for internal e-mail communications.

**Quality manager ISO 4.1.2.7**

The Quality Manager has responsibility for ensuring the quality management system is implemented and maintained, reporting to the Pathology Business Meeting and other management meetings and senior staff meetings on the functioning and effectiveness of the quality management system.

The Quality Manager is a part of the overall laboratory management team and, within this structure, oversees implementation, development and co-ordination of quality processes as described in the Quality Policy and this Quality Manual. This includes adherence to relevant professional standards and guidelines, and involvement with clinical governance issues and audit, as well as providing advice and being a focus for all issues relating to quality in the laboratory.
The Quality Manager must be aware of any current and evolving legislation and aim to ensure that quality systems meet the requirements of this legislation. The Quality Manager must identify and make the laboratory management team aware of any shortfall in resources. This relates to the use of staff and non-staff resources across the Pathology Service. The Quality Manager manages key aspects of the quality system e.g. document control, non-conformance management and ensures the promotion of awareness of users' needs and requirements throughout the laboratory organisation.

## 4. Quality Management system ISO 4.2

**General requirements ISO 4.2.1**

**Description and Scope of the Quality Management System (QMS)**

The QMS for Pathology is a set of co-ordinated activities to direct and control the department in order to continually improve the effectiveness and efficiency of its performance. Pathology runs the quality management system (QMS) as a vehicle to deliver a quality service. The QMS defines the organisational structure, responsibilities, policies, procedures, processes, standards, and resources required; it is not a static model, but a dynamic and evolving activity. Enshrined within the QMS is a commitment to continuous quality and process improvement with a patient focus. As part of the management of the QMS, Pathology has an appointed Quality Manager, and uses a software application called QPulse (Gael Quality) as an aid to fulfilling the requirements of the QMS.

Each element of the QMS is documented through policy, procedures and records stored in different approved formats within the appropriate module sections on the Qpulse system (see image below). All Pathology staff have access to some or all of

these modules depending on the level and type of access required but all Pathology staff must have access to the Documentation and CA/PA (corrective action/ preventative action) modules to perform their role effectively and to the correct standards.

## 5. Documentation requirements ISO 4.2.2

### General ISO 4.2.2.1

The creation of this Quality Manual provides documentary evidence of the existence of a quality management system (QMS). Laboratory management will endeavour to improve the effectiveness of this QMS in accordance with the requirements of ISO 15189:2012.

### Quality Manual ISO 4.2.2.2

This document serves as an index to laboratory documentation, provides an overview of the QMS implemented by the Pathology Service and also provides information for service users including accreditation bodies e.g. UKAS, MHRA, HTA etc.

It includes the Pathology Service Quality Policy (see 4.1.2.3 above), describes the scope of the QMS and sets out the organisation and management structure of the laboratory and its place within the Trust.
The Quality Manual includes a description of the roles and responsibilities of laboratory management. It is distributed to all staff using the QPulse software for them to read and acknowledge and instruction on the importance of the document forms part of the induction process for new staff.

## 6. Document control ISO 4.3

The Pathology Service utilises an electronic document management system (QPulse) to assure effective document control.

Document control and authorised modification is carried out according to QP/PA/GP002 Document Control within Pathology, to ensure that:

- All documents are reviewed at a frequency that ensures they remain fit for purpose and approved by authorised persons prior to use.
- Changes to documents are identified – handwritten amendments are not permitted.
- There is controlled access to the documents
- Current approved versions are available where needed and outdated documents removed and archived.

Archived documents are traceable to the originals and all other copies are destroyed.

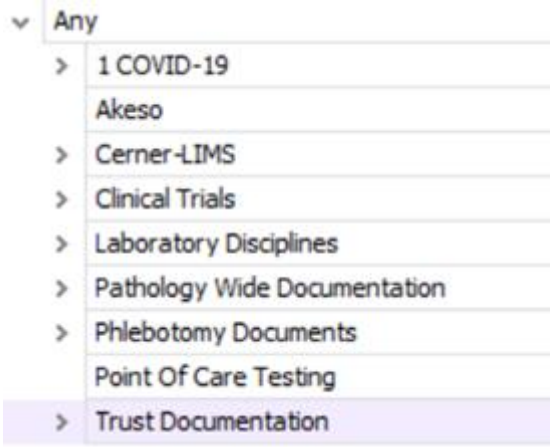
The masters of internally controlled documents are stored on the QPulse electronic document management system. They include the following:

- Pathology Services and Department specific policies
- SOPs and Pathology Services/Department management procedures
- Controlled forms including Risk assessments and COSHH
- Details of audits including identification of non-conformances and subsequent actions
- Records providing evidence of compliance with accreditation standards. This includes summaries of evidence available outside QPulse e.g. on the shared Pathology drive of the Trust IT system or as paper documents.

Minutes of meetings of Pathology Services Team, Operational Managers, Departmental meetings, Health & Safety, Training, Quality compliance and governance are stored on Qpulse.

QPulse also contains documents produced outside the control of the Pathology Service which are relevant to quality management, for example, documents from national recognized bodies e.g. Royal Colleges and specific information from commercial organisations. These documents are defined within this Quality Manual and/or listed within specific documents in QPulse.

The documents are identified into categories and stored on QPulse within categories:




The categories are then sub categoriesed into departmetnal documetns as outline:


## 7. Service Agreements ISO 4.4

All contracts and Service Agreements Pathology has signed up to must follow the Trust *Standing Financial Instructions* **[PROC/FIN/SFI]** this includes any agreements to provide medical laboratory services which is held by the Trust as a patient care contract with General Practitioners and Commissioners. Pathology also has a documented procedure to follow for Pathology specific service level agreements (i.e. blood transfusion services in the community) - *Procedure for the Establishment and Review of Service Level Agreements* **[QP/PA/GP010]**. All service level agreements will be documented fully.

### Establishment of service agreements ISO 4.4.1

Referral laboratories, external services, supplies and external advisory services are selected and evaluated as per standard operating procedure *Pathology Evaluation and Selection of Referral Laboratories or services* **[MP/PA/GP/REF001]**

### Review of service agreements ISO 4.4.2

Reviews of agreements include all aspects of the agreement and any changes are recorded and agreed by all relevant parties. If changes are necessary after the service has commenced, the review process must be repeated and any changes communicated to the affected parties. (QP/PA/GP010)

## 8. Examination by referral laboratories ISO 4.5

### Selecting and evaluating referral laboratories and consultants ISO 4.5.1

The procedure for the selection and evaluation of referral laboratories and consultants who provide opinions is described in Pathology Evaluation and Selection of Referral Laboratories or services (MP/PA/GP/REF001).

Arrangements with referral laboratories and consultants are reviewed and evaluated annually to ensure their continuing suitability. This is done by sending out MF/PA/GP002 Referral lab QMS request letter and recording the response under the appropriate record on the QPulse supplier module. The current UKAS accreditation status of each referral laboratory is also checked annually and recorded on QPulse.

Referral laboratory requests and results are scanned into the DART document storage and retrieval application and these records are kept for a minimum of three years.

**Provision of examination results ISO 4.5.2**

Unless otherwise specified in the agreement with the referral laboratory, each discipline within the Pathology Service ensures that the examination results from the referral laboratory are provided to the person making the request. All elements of the report from the referral laboratory are reported to the requestor without alterations that could affect clinical interpretation and the report states the source of those results. Where reference laboratory results are manually transcribed into the LIMS, a second check of the result is always performed before authorisation of the report. Regular workfile enquiries are performed to ensure that the stated turnaround times are being met.

## 9. External services and supplies ISO 4.6

Procurement of new equipment is undertaken in line with the County Durham and Darlington NHS Foundation Trust standing financial instructions and with the advice and support of the Trust Supplies and Finance Departments. The principles and practices of fair competitive tendering, value for money and suitability and ease of use will be used to guide each purchase.

All new equipment and/or processes are subject to evaluation, validation and qualification as appropriate before being put into routine use, with a process of change control to safely manage the period of implementation.

All pieces of equipment within Pathology Services are maintained either by the manufacturer or by the County Durham and Darlington NHS Foundation Trust Medical Engineering Department or other appropriate contractor. Calibration of equipment is carried out as per manufacturer's instructions, with details outlined in the appropriate SOPs.

The Pathology Asset Register identifies all those pieces of equipment which are on a service/maintenance contract, identifying the piece of equipment, serial number, contract number and maintains a log of any problems/call outs for the item. The

register is kept on Q-Pulse. All critical instruments have a local log where maintenance, engineer reports and calibration records are recorded and kept for the lifetime of the equipment.

The control of materials and selection of suppliers is described in

- LP/PA/HP/SOP125 Histology Procurement and Management of Equipment
- LP/PA/HT5 Haematology and Blood Transfusion Procurement and Management of Equipment
- LP/PA/CB/OP205 Biochemistry Procurement and Management of Equipment
- QP/PA/MB/PRO5 Evaluation, Verification and Introduction of New Equipment, Reagents and Consumables in Microbiology

Any performance issues relating to equipment, reagents, consumables or suppliers are raised as a CAPA on the asset or supplier module on QPulse, as appropriate.

The Pathology departmental managers delegate senior staff the responsibility to review the quality of reagents and material required; these are then ordered to maintain the appropriate stock level. The Pathology Service maintains a signatory structure of senior staff allocated with the appropriate authorities to order goods, reagents and specified sundry items to a specified amount not exceeding pre-determined parameters.

## 10. Advisory services (Clinical advice and interpretation ISO 4.7

Advice on test selection, sample type and turnaround times is available on the Pathology Service internet/intranet pages. Information on sample acceptance and rejection criteria may also be found on the internet/intranet pages within policy for sample acceptance and rejection QP/PA/GP/POL2.
In each discipline, a Consultant is available to offer clinical advice and interpretation. 24/7 cover is available in Biochemistry, Haematology and Microbiology. Consultant defined comments and procedures may be used. Each Consultant may seek advice from their Consultant colleagues or from recognized external experts.

## 11. Resolution of complaints ISO 4.8

All complaints are dealt with according to the Trust Complaints policy. The Trust will always aim to provide a full and thorough response to a complaint within 25 working days. However, on occasions it is reasonable to use the 25 days as a starting point due to the complexity of the case and/or the concerns raised.
Complaints are discussed at the discipline specialty groups and the departmental management meeting. A CAPA is also raised within QPulse to ensure the complaint is registered against the department.

The Trust policy on the handling of serious untoward incidents describes how Serious Incidents (SI) are managed so that the outcomes of such events provide a framework for learning. SIs are an event or series of events which have either a serious effect on the care of a patient or patients or the management of the Trust and include out of the ordinary or unexpected events and those likely to attract public and media attention. Appropriate practices and procedures must change in the light of lessons learned so that the likelihood of future recurrence is reduced. The Board of Directors will ensure that procedures are developed and, where necessary, reviewed and changed.

## 12. Non conformities ISO 4.9

The Trust has a Complaints and Concerns Policy POL/Comp/0003 that Pathology must adhere to and therefore Pathology has devised a standard operating procedure - Procedure for Control and Reporting of Non Conformities, Errors and Complaints QP/PA/GP005 which gives the procedures to follow when reporting and controlling non-conformities including errors and complaints with definitions and examples and describes the process for investigation, corrective action and preventative action.

Non-conforming examinations or activities can occur in many different areas and may be identified in many different ways, including complaints, IQA and EQA failures, instrument calibrations, equipment failures, reagent and consumables failures, internal and external audit and staff suggestions.

QP/PA/GP005 Procedure for control and reporting of non-conformities, errors and complaints describes the procedures in place to ensure that non-conformities in all processes are detected and managed to minimise risk to users. The clinical significance of non-conformities must be assessed by appropriately trained staff and results recalled where necessary. All non-conformities are recorded and reviewed within the discipline-specific areas of Pathology Services where the non-conformance was identified.

## 13. Corrective action ISO 4.10

Action taken at the time of a non-conformity to mitigate its immediate effects is considered “immediate” action. Only action taken to remove the root cause of the problem that is causing the non-conformance is considered “corrective” action.

QP/PA/GP005 Procedure for control and reporting of non conformities, errors and complaints describes the procedures in place to review and evaluate corrective actions.

## 14. Preventive action ISO 4.11

Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints i.e. non-conformances. In addition to the review of operational procedures, preventive action includes data analysis, trend and risk analyses and EQA.

QP/PA/GP005 Procedure for control and reporting of non-conformities, errors and complaints describes the procedures in place to eliminate the causes of potential non-conformances in order to prevent their occurrence.

## 15. Continual improvement ISO 4.12

The Pathology Service constantly strives to improve the service it offers and to ensure that it meets the changing needs of its users.

The Directorate strives to continually improve the quality of the service it provides including its own processes and communications. Quality improvement is achieved by a number of processes that together identify any potential risks, develop and implement corrective or preventative action plans and monitor effectiveness of these plans. These processes are user/stakeholder & staff feedback, audit, internal and external quality control and quality assurance, review and action on non-conformities including errors and complaints, review of suitability of procedures, processes and sample requirements, risk management, establishment of quality and key performance indicators, participation in clinical trials and research & development, change control.
The following procedures document how this is achieved:

- QP/PA/GP003 Procedure for internal audit
- QP/PA/GP004 Quality Indicators and Assurance Policy
- QP/PA/GP005 Procedure for control and reporting of non-conformities, errors and complaints
- MP/PA/GP/AMR6 Annual Management Review Process
- SP/PA/GP/DOC1 Pathology Health & Safety Policy
- MP/PA/GP/COM001 Pathology Communication Policy
- MP/PA/GP/011 Pathology Change Control Policy
- PRO/NG/0006 Visits, audits, inspections, assessments, reviews and accreditations by bodies external to the Trust, The Process

Training and education of staff is vital to the successful implementation of any developments, and all staff are encouraged to participate in the appropriate Continual Professional Development Schemes

To achieve this, Pathology Services participates in National Quality Assurance Schemes, monitoring of turnaround times, audit, user feedback, Corrective Action/Preventive Action and investigation of incidents.

The Departments each feed into the Pathology Services Annual Management Review, which outlines all the key developments and quality objectives planned for the forthcoming year. This dovetails into the key objectives from the Trust Business plan. Areas of achievement are also recorded in the annual review. See MP/PA/GP/AMR6 Pathology Annual Management Review.

Results of audit and improvement processes are disseminated to staff and to service users where appropriate
Quality improvement is achieved by a number of processes that together identify new examinations, remove ineffective practice and assess potential risks, develop and implement corrective or preventive action plans and monitor effectiveness of these plans. Investigation of serious untoward incidents (SUI's) includes root cause analysis.
Training and education of staff is vital to the successful implementation of any developments, and all staff are required to participate in the appropriate Continual Professional Development Schemes.

## 16. Control of records ISO 4.13

The control of process and quality records is aided by use of the Q-Pulse Quality Management software and follows current guidance supplied by NHS Records and the Royal College of Pathologists (RCPath) The retention and storage of pathological records and specimens, located within the Publications and Media section of the RCPath website.

It is the responsibility of the Quality Assurance Manager to ensure that the quality records are established and maintained.

All Departmental Heads are responsible for ensuring that all staff in their departments are familiar with and use the document management system as described in the Document Control procedure QP/PA/GP/002 and each laboratory document for the control of process & quality records and the control of clinical material. These laboratory specific standard operating procedures can be found within the QPulse document menu, within the Pathology Documentation - Laboratory section.

All documents are electronic unless printed for backup purposes or for display within Pathology but not all records will be electronic as some will be paper based (i.e. fridge charts, NEQAS reports etc.). All clinical material will be considered a biohazard unless otherwise specified within the SOPs, Health & Safety documentation or risk / COSHH assessments. SOPs are stored in the electronic document management system. Access to create or amend SOPs is given to those staff authorised to do so. Other staff have access to read these documents but not amend or create new ones. The Quality Manager responsible for ensuring that all staff in the departments are familiar with and use the Process Control and Quality Records systems (QPulse).

Request forms and other paper records e.g. NEQAS results, old SOPS etc. are stored according to NHS guidelines on data storage and protection in boxes within the laboratory short term and long term or in a secure off site facility.

Records are retained in line with The Royal College of Pathologists guidelines on the Retention and Storage of Pathological Records and Archives 5th edition 2015 QP/PA/GP/EXT001 and Department SOP's

There is a legal requirement under Blood Safety and Quality Regulations (BSQR) to retain blood component traceability records for 30 years and processes are in place to do this.

Human Tissue Act regulations state that sites must be licensed to perform scheduled activities.

## 17. Evaluation and Audit ISO 4.14

### General ISO 4.14.1

To ensure that the quality management system (QMS) within Pathology Services continues to function as required, the laboratory has planned and implemented the evaluation and internal audit processes needed to:

- Demonstrate the pre-examination, examination and post examination and supporting processes are being conducted in a manner that meets the needs and requirements of users.
- Ensure conformity to the QMS.
- Continually improve the effectiveness of the QMS.

This process is described in MP/PA/GP003 Procedure for Internal Audit.

### Review of requests, suitability of procedures and sample requirements ISO 4.14.2

The repertoire of the laboratory is continually reviewed to ensure tests remain clinically relevant especially when new tests are introduced which may make older tests obsolete. These reviews take place at the departmental meetings in each discipline. Sample volumes and preservatives required are made clear to users of the service by being printed on the ICE request form and available on Pathology Service pages of the intranet and internet sites.

### Assessment of user feedback ISO 4.14.3

The Pathology Service participates in user satisfaction activities. The results of these activities identify any problems or deficiencies in the service offered. There is a link to a user survey sent annually to all service users to complete. User satisfaction is also assessed by personal contact, formal meetings between laboratory staff and

users and by interaction in seminars, MDTs etc. Such meetings are minuted where possible and recorded in the minutes.

**Staff suggestions ISO 4.14.4**

Staff are encouraged to make suggestions for service improvement/preventive action, see QP/PA/GP005 Procedure for control and reporting of non conformities, errors and complaints. They may make suggestions in a number of ways, including document change requests, at staff huddles/meetings, raising a QIN on Qpulse.

**Internal audit ISO 4.14.5**

The cycle for internal auditing must be completed in one year. It is not necessary for internal audits to cover all elements of the QMS in depth each year as it may be that the laboratory decides to focus on a particular activity, but it must do this without neglecting other activity types.

Audits are conducted by personnel who have been trained to assess the performance of managerial and technical processes of the QMS. Auditor selection must ensure that the conduct of audits is objective and impartial and where possible, that they are independent of the activity to be audited.

Internal audits are conducted at planned intervals in order to determine whether all activities in the QMS, including pre-examination, examination and post- examination conform to the requirements established by the laboratory and ISO15189:2012 and ensure that these requirements are implemented, are effective and are maintained.

Personnel conducting audits must ensure that appropriate corrective action is promptly undertaken when non-conformances are identified.
See QP/PA/GP003 Procedure for internal Audit and QP/PA/GP005 Procedure for control and reporting of non conformities, errors and complaints.

**Risk management ISO 4.14.6**

The evaluation of the impact of work processes and potential failures on examination results which may affect patient safety is monitored following MP/PA/GP/PRO2 Risk Management

**Quality indicators ISO 4.14.7**

Monitoring of turnaround times is carried out as part of the quality systems in place for each Department. Any local turnaround issues are discussed at the Departmental speciality meetings and acted upon accordingly.

All critical internal processes are audited regularly to ensure compliance with regulations and conformance to local procedures. See QF/PA/GP004 Quality Indicators and Assurance Policy.

**Reviews by external organisations ISO 4.14.8**

The Laboratory is currently assessed by external organisations including:

- Care Quality Commission (CQC) http://www.cqc.org.uk/
- Health and safety executive (HSE) http://www.hse.gov.uk/
- Medicines and Healthcare Products Regulatory Agency (MHRA) https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- Human Tissue Authority (HTA) https://www.hta.gov.uk/codes-practice
- United Kingdom Accreditation Service (UKAS) http://www.ukas.com/
- National Blood and Transplant Authority http://www.nhsbt.nhs.uk/
- United Kingdom National External Quality Assessment service http://www.uknegas.ucl.ac.uk/
- Institute of Biomedical Sciences https://www.ibms.org/
- Health Protection Agency https://www.gov.uk/government/organisations/health-protection-agency

Where reviews by external organisations indicate that the Pathology Service has non-conformances or potential non-conformances, the laboratory takes the appropriate immediate actions and, when necessary, the appropriate corrective and preventive actions in order to comply with the requirements of ISO15189:2012. These non-conformances and associated actions are recorded in the CAPA module on QPulse and they are reviewed at the Pathology Quality Management meeting and the relevant Departmental quality and speciality meetings. See QP/PA/GP005 Procedure for control and reporting of non-conformities, errors and complaints and the minutes of meetings on QPulse.

## 18. Management review ISO 4.15

**General ISO 4.15.1**

All aspects of service quality are subject to appropriate monitoring as part of the day to day management of Pathology Services. In-year major new developments or service changes or service failures are reviewed and determined at the annual management review meeting. See MP/PA/GP/AMR6 Annual Management Review Process.

**Review input ISO 4.15.2**

Records are kept and key objectives for subsequent years defined and plans formulated for their implementation. The records are kept with the Service Manager and Quality Manager as appropriate. The procedure for the Annual review is described in MP/PA/GP/AMR6.
Each department will complete an annual review and identify objectives and performance and quality indicators and these will be discussed in relation to the Directorate review.
The Laboratory Management Team conducts an annual review which considers the following items of information from the preceding year:

- Reports from managerial and supervisory personnel
- Assessment of user satisfaction and complaints
- Staff suggestions
- Internal audit of the quality management system and examination processes
- Review of requests and suitability of procedures and sample requirements
- External quality assessment reports
- Performance of suppliers
- Reports of assessments by outside organisations
- Status of preventive, corrective and improvement actions
- Major changes in organisation and management, resource (including staffing) or processes
- Follow-up actions from previous management reviews
- Recommendations for improvement.

**Review activities ISO 4.15.3**

The review input information described above is discussed at the annual management review meeting and is analysed for trends and patterns that indicate trends or process problems. Any necessary changes to the quality management system, including the quality policy, are also discussed.

The Pathology Service formulates quality objectives for each year which are submitted for discussion and acceptance by the Pathology Management Team. These include, and are directly related to, the objectives of the Pathology Services as a whole and those of the Trust and focus on the laboratory's contribution to patient care. See MP/PA/GP/QO3 Pathology Quality Objectives.

**Review output ISO 4.15.4**

The review of the Pathology departments are documented using a varied documents approach, Pathology Quality Assurance Dashboard (PQAD), Pathology Quality Management System Audit (PQMS) Departmental Quality objectives (individual records can be found on Qpulse and are combined to form the Annual Management

Review which is recorded in the following documents which may be found on QPulse:

- MP/PA/GP/AMR6 Annual Management Review Process
- QF/PA/GP046 Annual Management Review Template
- MP/PA/GP/QO3 Quality objectives Procedure
- MP/PA/GP/QO4 Departmental Quality Objectives Template

The Departmental annual management review is distributed to all staff on QPulse for acknowledgement; the other documents are distributed to the appropriate personnel.

## Technical Requirements ISO 5

### 19. Personnel ISO 5.1

### General ISO 5.1.1

All Departments are Consultant lead, with a Lead Biomedical Scientist in technical charge of the laboratory. A team of State-registered professionally qualified Biomedical scientists with Department Managers leading sections of each laboratory provide the backbone of the workforce, together with Advanced Practitioners, Transfusion Practitioner and Medical Technical Officers, Mortuary Technicians, associate transfusion practitioners, assistant practitioners (Band 4) and Medical Laboratory Assistants, all working under the guidance of qualified staff. Administrative and clerical support is available both at the Directorate and departmental level. As Pathology is part of the larger entity CDDFT, the department follows the Human Resources and Organisational Development Policies and procedures of CDDFT located on the Trust Staffnet as shown below.

These documents include:

- PROC/PD/0003 *Recruitment Selection procedure*
- PROC/PD/0025 *Employment Checks*
- POL/PD/0025 *Management of Employee personal file information*
- POL/PD/0051 *Induction*
- POL/PD/008 *Education, Learning, Development (study leave) policy*
- POL/PD/013 *Appraisal*
- POL/PD/0053 *Training needs analysis monitoring & Evaluation*
- POL/PD/0018 *Staff communications*
- POL/PD/019 *Working time regulations*
- PROC/PD/009 *Disciplinary Procedure*

All documents relating to staff will be accessed and stored as described in the procedures and all staff will be appropriately training and competency assessed as appropriate to the staff role and grade and as per the local procedure for each

department (see QPulse, Pathology, Laboratory section for laboratory specific SOPs).

Pathology has an *Education and Development Training Policy* MP/PA/GP/TR001 which recognises the training and development required for Pathology Staff.

**Personnel qualifications ISO 5.1.2**

All BMS staff must be registered with the Health and Care Professions Council (HCPC). The Trust Electronic Staff Record (ESR) notifies Departmental Managers of pending or lapsed registration.

The qualifications required for each post are detailed in the relevant job description and reflect the education, training, experience, knowledge and skills appropriate to the role.

The personnel making judgements with reference to examinations have the applicable theoretical and practical background and experience, in accordance with national, regional and local regulations and professional guidelines.

**Job descriptions ISO 5.1.3**

The job descriptions for all grades of staff are available on QPulse for reference. Each member of staff has a copy of their appropriate job description in their personnel file and it is reviewed at their annual staff appraisal.

**Personnel introduction to the organizational environment ISO 5.1.4**

The laboratory has an induction programme to introduce new staff to the organisation. See MP/PA/GP/TRA/002 Generic Induction for all staff.

**Training ISO 5.1.5**

All disciplines are approved for the training of Biomedical Scientists by the Institute of Biomedical Science (IBMS). All staff are encouraged to participate in internal and external courses, with funding provided as appropriate.

Prior to participation in a course, an internal Trust study leave request form is filled in by the participant and kept in their personal file.

A record is maintained in each member of staff's CPD file of their attendance on courses or at meetings. Details of attendance at mandatory training can be accessed electronically for each member of staff via the trust Electronic ESR portal.

All trainee BMSs undertake an internal training programme which links to the HCPC registration portfolio. There is nominated training officer for each department with an

overarching pathology training lead. During the training period each trainee has a nominated mentor who is responsible for ensuring that their training needs are met. The Training Officer and mentor are responsible for ensuring that all portfolios and Training Manuals are kept updated during the course of training.

All staff are trained using structured training manuals specific for the area and the roles of the individual and are supervised at all times whilst undergoing training.

The training for all personnel includes:

- Ethics QF/PA/GP/EC001 Ethical conduct form
- Quality management QP/PA/GP/SI2 Quality and accreditation for pathology staff management system
- Assigned work processes and procedures – see the training documents for each discipline on QPulse.
- The laboratory information system – see QPulse for IT documentation.
- Health and safety – see SP/PA/GP/DOC3 Health and Safety Manual
- Confidentiality of patient information – see trust Information governance policies

**Competence assessment ISO 5.1.6**

Existing staff competence is assured and documented through a structured competence process specific for area and role. Competency documents for each discipline may be found on QPulse.

Competency is assessed over a rolling 2 year cycle and may include:

- Direct observation of routine work processes and procedures
- Monitoring of the reporting and recording of examination results
- Review of work records
- Assessment of problem-solving skills
- Examination of specially provided samples e.g. previously examined samples, EQA samples

**Review of staff performance ISO 5.1.7**

This is conducted using the procedures of the Trust Appraisal policy. The system follows a cascade from the Trust Board through the Medical Director, Department clinical heads, Pathology General Manager, Service and Departmental Managers and on to all other staff groups.

All staff are appraised each year, where an agreed set of objectives based upon the departments needs and the personal development needs of the individual are set. Agreed personal development plans (PDP) are used to help in the submission of the

Training Needs Analysis each year to the Training & Development department, to enable planning of both in-house and external training required for the year.

All additional training and development opportunities are highlighted and actioned through the Appraisal process.

All staff conducting appraisals are appropriately trained.

**Continuing education and professional development ISO 5.1.8**

The Pathology Service provides update and training sessions for all staff. These are certificated on attendance or on completion, with the records being kept on Qpulse. Each individual is responsible for maintaining their own CPD record.

Within the departments are numerous text books and journals available to staff. There is also access to the Internet. The Trust Learning, Research and Innovation Centre can be used for obtaining papers from journals not kept on site. There are facilities for staff to study in the 'library' and time is also allocated for staff projects as part of their studies.

**Personnel records ISO 5.1.9**

Staff records are kept as hard copies by the individual Department Manager. The personal file for each member of staff is maintained by the Department manager, these are kept in a secure file located in the Department manager's office, with access being strictly controlled.
Each personal file contains the following information:

- Personal details
- Record of induction
  - Staff engagement / employment information
  - Job description
  - Educational and professional qualifications
  - Sick leave / occupational health records / accident records
  - Staff Development Review details
  - Change of circumstances details.
  - Grievance and disciplinary details
  - Immunisation records

Training, competency and continuing education and achievement records are kept by each individual staff member in their training file.

## 20. Premises (ISO 5.2)

The University Hospital of North Durham and Darlington Memorial Hospital provides a working environment in which staff can perform required functions in accordance with national legislation and guidelines.

## Accommodation and environmental conditions ISO 5.2.1

The laboratories have space allocated for the performance of work which is designed to ensure quality, safety and efficacy of the service to the users and the health and safety of laboratory personnel and visitors to the department (i.e. visitors, patients, Trust estates personnel, equipment engineers and other contractors as required). Pathology provides a working environment in which staff can perform required functions in accordance with national legislation and guidelines and access is restricted by coded lock doors, to authorised visitors and personnel only. The sufficiency and adequacy of space is reviewed regularly through audit and review of services and processes. There is no area identified for sample collection within any of the Pathology departments as this service is not currently provided by the department. As the laboratories are part of a larger Trust there are Trust wide Estates and Facilities procedures and policies available on the Staffnet site within the Policies and Procedures Section. The Pathology Service provides adequate and well managed space for the functioning and use of all laboratory equipment and services.

The laboratory complex has been designed to ensure access to

- Adequate services such as power (including emergency), heating, lighting, drainage and water supply
- Appropriate facilities for waste disposal
- Communication systems e.g. phone and bleep
- Safety systems e.g. fire detection and alarm systems, fire-fighting equipment, emergency door release mechanisms for cold rooms, spillage kits where appropriate and eye wash facilities.

Staff are required to maintain good housekeeping at all times, with the environment kept clean and tidy.

Environmental conditions are monitored where they may have an impact upon the quality of result obtained e.g. temperature in areas where reagents and samples are stored and laboratory areas where a defined temperature range is required for operation of equipment.

## Lab and office facilities ISO 5.2.2

Access to the Pathology laboratories at UHND and DMH is controlled and restricted to authorised personnel only. Access is via electronic number keypad coded locked doors to ensure that medical information, patient samples and laboratory resources are safeguarded from unauthorised access. Public areas at the front of the Pathology suite allow a separate waiting area for visitors.

The Mortuary is located separately to the Pathology laboratories at UHND and DMH. At UHND by locked number coded security door and DMH access is via electronic swipe card security locked doors

Access to areas within and associated with Pathology, such as Blood issue fridges and Containment Level 3 facilities, are also controlled to ensure access to appropriate Trust staff only.

Separate office facilities are available within the Pathology laboratories for those staff performing administrative duties and there is a seminar room for meetings/ educational activities. .

**Storage facilities ISO 5.2.3**

There are a number of storage areas within the Pathology Service. These include:

- Chemical storage cabinets containing flammable liquids and corrosives.
- Cold rooms for reagents.
- Separate cold rooms for specimen storage.
- Local refrigerators for current specimens and reagents.
- Common store room for consumables and other laboratory items.
- All facilities that require temperature monitoring have appropriate monitoring systems in place to assure correct temperature maintenance.
- Outside storage sheds located at the rear of Pathology for the storage or consumables and waste.

Each department maintains stock control system for kits, reagents and control materials.

**Staff facilities ISO 5.2.4**

Each hospital site has a Staff Cafeteria for meals and snacks and within both laboratories there is a staff rest room where staff can prepare their own refreshments. Access to the internet and computer facilities are available to all staff.

There are staff facilities which include:-

- sufficient toilet accommodation including facilities for disabled users
- basic catering facilities and access to a supply of drinking water
- a secure locker storage for personal effects
- storage for protective clothing
- safe and secure working arrangements
- plentiful hand washing facilities

**Patient sample collection facilities ISO 5.2.5**

There is a separate reception area at both sites for patients and visitors to the Service. There are also W.C. facilities that can be accessed visitors. There are no

facilities for specimen collection or phlebotomy within the laboratory precincts. Phlebotomy and treatments are performed in other appropriate areas of the hospital.

**Facility maintenance and environmental conditions ISO 5.2.6**

All facilities that require temperature monitoring have appropriate monitoring systems in place to assure correct temperature maintenance.

Electrical safety checks are carried out on a regular basis by the Trust maintenance staff and all equipment is marked, identifying the last inspection date and when the next inspection is due.

At all sites, the following services are delivered:

- Cleaning
- Property services, including building maintenance
- Laundry
- Portering
- Car parking and security management

## 21. Equipment, reagents and consumables ISO 5.3

For the purposes of this document, and to comply with ISO15189:2012, laboratory equipment includes hardware and software of instruments, measuring systems and laboratory information systems; reagents include reference materials, calibrators and quality control materials and consumables include culture media, glass slides, pipette tips etc.

The laboratories are furnished with equipment needed for the provision of services and for laboratory equipment and reagents this is through a 10 year managed service contract with Siemens, the contract includes periods of review and includes a refresh at 5 years. The procedures for selection and purchasing of equipment are as part of the trust Standing Financial Instructions PROC/FIN/SFI following full tender processes as required. Management of equipment is documented through local Laboratory procedures and manufacturers information (External documents within QPulse) and will include acceptance testing, instructions for use, calibration & metrological traceability, maintenance & repair, adverse incident reporting and equipment record documentation.

The laboratories have documented procedures for the reception, storage, acceptance testing, inventory management, appropriate use and adverse reporting and record maintenance for reagents and consumables. These documents are within the laboratory section of QPulse and may be within Equipment or Laboratory Procedure documents.

**Equipment ISO 5.3.1**

**General ISO 5.3.1.1**

See the below documents for the Pathology Service procedure for the selection, purchasing and management of equipment.

- LP/PA/HP/SOP125 Histology Procurement and Management of Equipment
- LP/PA/HT5 Haematology and Blood Transfusion Procurement and Management of Equipment
- LP/PA/CB/OP205 Biochemistry Procurement and Management of Equipment
- QP/PA/MB/PRO5 Evaluation, Verification and Introduction of New Equipment, Reagents and Consumables in Microbiology

The laboratory is furnished with all equipment needed for the provision of services. Equipment in need of replacement is placed on the Trust capital replacement list. Procurement of new equipment is undertaken in line with the Trust standing financial instructions and with the advice and support of the Trust Supplies and Finance Departments. The principles and practices of fair competitive tendering, value for money, suitability and ease of use are used to guide each purchase.

**Equipment acceptance testing ISO 5.3.1.2**

All new equipment and/or processes are subject to evaluation, validation and qualification as appropriate before being put into routine use, with a process of change control to safely manage the period of implementation.

Every piece of equipment is given a unique reference number by the Trust Medical Engineering department and is also given a QPulse asset register number.

**Equipment – instructions for use ISO 5.3.1.3**

Manufacturer's operating and maintenance manuals are held in the relevant section of the laboratory. Where necessary the manufacturer's manuals are supplemented by documented in-house methods with information pertaining to the operation, maintenance and calibration of such equipment incorporated into the SOP.

All members of staff are given instructions on using the equipment and know the appropriate internal "house-keeping" measures.

**Equipment calibration and metrological traceability ISO 5.3.1.4**

Calibration of equipment is carried out as per manufacturer's instructions, with details outlined in the appropriate SOPs. Instrument SOPs also document how the metrological traceability of the calibration standard used and the chain of calibration of the instrument is recorded.

**Equipment maintenance and repair ISO 5.3.1.5**

Equipment on reagent rental is maintained by the supplier. All other equipment maintenance is co-ordinated by the departments to negotiate the service contract interval, cost and type of service on behalf of the Pathology Service.

Electrical safety checks are carried out on a regular basis by Trust maintenance staff and all equipment is marked, identifying the last inspection date and when the next inspection is due.

**Equipment adverse incident reporting ISO 5.3.1.6**

Instrument faults must be recorded as a non-conformance on the asset record in QPulse and it must be ensured that the fault has not affected examination results. If examination results have been affected by the equipment defect, then a Ulysses incident form must be submitted and Trust policy Incident Reporting must be followed.

**Equipment records ISO 5.3.1.7**

An up to date inventory of equipment is maintained and reviewed to identify which items of equipment need replacing. The inventory lists date of purchase, price (where available) and serial number.

The Pathology Asset Register on QPulse identifies all those pieces of equipment which are on a service/maintenance contract, identifying the piece of equipment, serial number, contract number and maintains a log of any problems. All critical instruments have a local log where maintenance, engineer reports and calibration records are recorded and kept for the lifetime of the equipment.

**Reagents and consumables ISO 5.3.2**

**Reagents and consumables - General ISO 5.3.2.1**

It is essential to have proper management of all materials used in the laboratory from receipt to the end fate of the reagent.

All procedures have assigned COSHH and Risk Assessments for the handling and safe disposal of any hazardous materials involved.

**Reagents and consumables - Reception and storage ISO 5.3.2.2**

When delivery of reagents and materials is taken, they must be appropriately logged and documented prior to being stored correctly to ensure a full audit trail is achieved. It is particularly important with reagents that they are stored in date order and according to lot number to ensure batch continuity.

**Reagents and consumables - Acceptance testing ISO 5.3.2.3**

Materials received must be in an acceptable condition and proved to be working correctly prior to use. Testing materials and reagents as soon as possible after receipt maintains control of this process and if any problems are highlighted, they can be dealt with promptly to minimize any potential disruption to the laboratory e.g. faulty or damaged reagents can be replaced by the supplier before the current reagents expire.

**Reagents and consumables - Inventory management ISO 5.3.2.4**

The inventory control system in place ensures that uninspected and unacceptable reagents and consumables are segregated from those that have been accepted for use.

**Reagents and consumables - Instructions for use ISO 5.3.2.5**

The current version of a kit insert or instruction for use must be readily available. Instructions may be stored in paper form or in the document register on QPulse.

**Reagents and consumables - Adverse incident reporting ISO 5.3.2.6**

Reagent and consumable faults must be recorded as a non-conformance on the supplier record in QPulse and it must be ensured that the fault has not affected examination results. If examination results have been affected by the reagent or consumable defect, then a Ulysses incident form must be submitted and Trust policy Incident Reporting must be followed. Laboratory management must be informed immediately of any erroneous results so that they may take the appropriate corrective actions.

**Reagents and consumables - Records ISO 5.3.2.7**

Records are maintained for each reagent and consumable that contributes to the performance of examinations. These records include:

- The identity of the reagent or consumable
- The manufacturer and batch/lot number
- The date of receipt
- The expiry date
- The date of entering into service
- If applicable, the date the material was taken out of service
- The condition when received e.g. acceptable, damaged

- The results of acceptance testing
- On-going acceptance records
- Where the reagent is prepared or completed in-house, the name of the staff undertaking the preparation and the date this occurred.

See Qpulse for individual departmental record templates

## 22. Pre-examination processes ISO 5.4

### General ISO 5.4.1

Pathology has its own section within trust internet site for information for internal users and patients. The Pathology Electronic Handbook which contains information for Patients and users of the services. Each department has a section in the Pathology Users Handbook which describes the range of tests offered by the department, contact & request form information, primary sample collection and handling, sample transport etc. (Click on image below to go to the internet page)

The laboratory has procedures for sample reception and pre-examination handling, preparation and storage which are within the Pathology documents, laboratory section on QPulse.

The laboratory has documented procedures and information for pre-examination processes to ensure the validity of the results of examinations and these are described below.

### Information for patients and users ISO 5.4.2

The Pathology Service website provides detailed information for all service Users. It is maintained by the Pathology Quality team and is available on the County Durham and Darlington Foundation Trust intranet https://www.cddft.nhs.uk/our-services/division-of-clinical-support-services/pathology.aspx

The website contains the following information:

- The location of the laboratory
- The laboratory opening hours
- Contact telephone numbers and email addresses of key personnel
- The types of clinical services and examinations offered by the laboratory, including tests referred to other laboratories
- Information on patient preparation and special precautions
- Information on required sample volumes and specimen collection
- Turnaround times
- Instruction on request form completion
- Specimen transport instructions
- Specimen acceptance and rejection criteria

- The availability of clinical advice
- The policy on consent and protection of personal information
- The complaints procedure

The Pathology intranet website is updated regularly by the Pathology Quality Team. Procedures related to the maintenance and control of user information on the pathology internet site are described in LP/PA/GP002 Procedure for Document Preparation and Control Policy.

Each department is happy to answer telephone queries regarding any test information from users.

Explanations on specific preparation for testing, explanation of specific procedures and the expected duration of the test and the availability of results are available upon request, using a suitable medium and language to facilitate understanding.

**Request form information ISO 5.4.3**

The electronic order communication system ICE (an interop requesting/reporting system using Systm1 or EMIS) is used for almost all requests from primary care for Biochemisty, Haematology, Immunology and Microbiology. A multi-discipline manual form is available for users who do not have access to the ICE or for when the system is out of use. This has been designed for ease of use and mirrors the data fields on the ICE system.
The request forms allow space for the following information:

- Patient identification, including gender, date of birth and patient location
- Unique patient identifier e.g. NHS number and hospital number
- The name of the requestor and the destination for the report
- The type of primary sample and, where relevant, the anatomical site of origin
- The date and time of specimen collection
- The examinations requested
- Clinically relevant information about the patient and request
- The date and time of specimen receipt in the laboratory

Request forms which are incomplete or incorrect are rejected, the requestor being informed either by telephone or by receipt of a standard request rejection (with appropriate reason). See QP/PA/GP/POL1 Specimen Acceptance and Rejection Policy.

The Pathology Service will not accept responsibility for incorrect patient information details of acceptance and rejection criteria are contained within the relevant SOP's. For certain types and categories of samples acceptance /rejection is at the discretion of a senior member of staff.

**Primary sample collection and handling ISO 5.4.4**

**General ISO 5.4.4.1**

All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents herself/himself at a clinic with a request form and willingly submits to the usual collection procedure e.g. venepuncture. Patients in a hospital bed should normally be given the opportunity to refuse, except in emergency situations where consent may not be possible.

The Pathology Service is responsible for the phlebotomy service. The taking of samples by other staff groups falls outside the role of the Pathology Service.

Consultant staff are available for consultation throughout the day and scientific staff in biochemistry, haematology and microbiology are available in the laboratory twenty four hours every day.

The Pathology Service periodically reviews its sample volume requirements and other details of sample collection in consultation with users and takes guidance from the following sources: NICE, Clinical audits, Cancer network guidelines, MDT and Directorate meetings.

**Instructions for pre-collection activities ISO 5.4.4.2**

The requirements of the department in terms of the correct completion of the request form, specimen requirements and handling of high risk specimens are outlined on the Pathology Service website available on the Trusts intranet and internet site.

**Instructions for collection activities ISO 5.4.4.3**

Instructions for specimen collection activities may be found on the Trust internet/intranet sites.

**Sample transportation ISO 5.4.5**

The Pathology Service follows the Specimen Transport policy SP/PA/GP/POL1.

Regular audits are carried out to monitor the temperature during specimen transport to ensure the integrity of the specimen.

**Specimen reception ISO 5.4.6**

The following documents describe the receipt of the specimen within out departments:

- LP/PA/MB/REC1 Specimen Reception: Receipt of Specimens in Microbiology
- LP/PA/HP/SOP99 Receipt of Specimens in Histology
- LP/PA/CY/SOP62 Non-Gynae Specimen Reception in Cytology

- LP/PA/GR001 Receipt of samples in Blood sciences.

QP/PA/GP/POL2 Sample and Acceptance Protocol for Pathology describes the criteria for sample acceptance or rejection.

All samples received are entered onto the LIMS system which has a full audit trail covering the date and time of receipt/registration and the identity of the person receiving the sample.

**Handling, preparation and storage ISO 5.4.7**

Access to the laboratories at UHND and DMH is controlled and restricted to authorised personnel only. Access is via electronic security coded locked doors to ensure that medical information, patient samples and laboratory resources are safeguarded from unauthorised access.

The laboratory has refrigeration and storage facilities for specimens to avoid deterioration during pre-examination procedures.

Time limits for requesting additional examinations or further examinations on the same primary sample are shown on the Trust internet/intranet sites.

## 23. Examination processes (ISO 5.5)

**Selection and validation of examination procedures ISO 5.5.1**

**General ISO 5.5.1.1**

The range of examinations offered by Pathology Services ensures that a suitable service is provided to our users. The range of tests available is constantly reviewed in departmental management meetings. Where appropriate, anticipated changes are discussed with service users.

A list of tests available is given on the Trust Intranet Site within the Pathology Handbook and Test Directory. Participation in audit, peer review, Internal Quality Assurance (IQA) and the participation in appropriate External Quality Assessment/Assurance (EQA) schemes all assist in verification and where required validation of examination procedures.

All examination procedures used within the Directorate have an associated SOP. These documents detail the method to be followed, reagents/materials required, quality control, Health & Safety issues and include all of the requirements of ISO

15189:2012 standard 5.5.3 Documentation of examination Procedures. Some hard Copies of SOPs are located in the appropriate workstation, master copies are available on Q-pulse. All SOPs are kept as controlled documents and any reviews are dealt with following the agreed Pathology document control procedure.

All examination procedures include analysis of internal quality control material/ procedures and where appropriate, participate in EQA schemes. Monitoring of performance is carried out in laboratory meetings and for EQA by an annual audit of results by Speciality Group Meetings. IQA is reviewed monthly as outlined in the appropriate SOP. All departments record any non-conformities as per the standard operating procedure QP/PA/GP005**.** These are reviewed by the laboratory management, and a report is given at the monthly at the specialty meetings. Areas for concern are discussed and any change of working practises are reviewed as required.

A list of documents for each discipline can be requested from QPulse through the document module, search facility (search for the document type specific for the discipline) and from the main menu select “print” and this will give a PDF version of the selected list for printing or emailing.

**Verification of examination procedures ISO 5.5.1.2**

All new or modified processes are validated to ensure that the service delivered is of a high standard and there are systems to ensure that the validated status is maintained. The laboratory obtains information from the manufacturer to confirm the performance characteristics of the procedure and confirms, through objective evidence, that the performance claims for the examination procedure have been met.
See:

- LP/PA/HP/SOP112 Validation and Verification of Equipment and Procedures in Cellular Pathology
- LP/PA/CB/OP211 Biochemistry Verification Policy
- LP/PA/CB/OP222 Biochemistry Validation Procedure
- LP/PA/CB/VVEXT Biochemistry Validation and Verification for 3rd Party Kits
- LP/PA/TR7 Blood Transfusion Validation Policy
- LP/PA/HA156 Haematology Validation Policy
- QP/PA/MB/PRO5 Evaluation, Verification and Introduction of New Equipment, Reagents and Consumables in Microbiology

**Validation of examination procedures ISO 5.5.1.3**

Participation in audit, peer review, participation in appropriate external quality assessment schemes and attendance at national and local seminars assist in validation of examination procedures.

The laboratory validates:

- Non-standard methods
- Laboratory designed/developed methods
- Standard methods used outside the intended scope
- Validated methods that are subsequently modified.

**Measurement uncertainty of measured quantity values ISO 5.5.1.4**

The laboratory has documented procedures for determination of measurement uncertainty for each measurement procedure. See:

- QP/PA/MB/PRO3 Traceability and Measurement of Uncertainty in Microbiology
- LP/PA/HA92 Haematology traceability and Uncertainty of Measurement
- LP/PA/TR93 Blood Transfusion Uncertainty of Measurement
- LF/PA/CB/OP/112 Clinical Biochemistry Uncertainty of Measurement Review Document
- LP/PA/CY/SOP82 Measurement of Uncertainty within Cytology
- LP/PA/HP/SOP64 Measurement of Uncertainty within Histology
-

Upon request, the laboratory makes its estimates of measurement uncertainty available to users of the Service.

**Biological reference intervals and clinical decision values ISO 5.5.2**

Biological reference intervals have been derived for examination procedures where relevant and their source documented. They are available via reports and Pathology handbook. Reference intervals are reviewed whenever an examination technique is changed and the Trust internet/intranet site is updated as changes in service occur. Users are informed when results or their interpretation may be significantly different.

- LP/PA/CB/OP202 Biochemistry Reference Range Sources
- LP/PA/HA139 Haematology Reference Range Sources
- LF/PA/MB/FORM116 Standard Microbiological Investigations (Normative References)

**Documentation of examination procedures ISO 5.5.3**

All examination procedures used within Pathology Services have an associated Standard Operating Procedure (SOP). These documents detail the method to be followed and other relevant information, according to the table of contents. Hard copies of SOPs are located in the appropriate section, with the master copy on the QPulse electronic document management system.

All SOPs are kept as controlled documents and any reviews are dealt with following agreed Pathology document control procedures – see LP/PA/GP002 Procedure for Document Preparation and Control.

Prior to implementing a new technique, an SOP, COSHH and risk assessment (if appropriate) must be completed and stored on QPulse. Reference is made to any risk assessment in the SOP. SOPs are maintained as read only documents in QPulse and updated through the change request process. Documents are distributed to staff who require knowledge of that process as part of their role and are read then acknowledged in QPulse. A standard template for SOPs is used – see QF/GP/PA/TEMP1 SOP Template Examination and QF/GP/PA/TEMP2 Policy/ Procedure Template- Non Examination SOP.

## 24. Ensuring the quality of examination results ISO 5.6

### General ISO 5.6.1

The laboratory ensures the quality of examinations by performing them under conditions defined in the relevant SOP.

### Quality control ISO 5.6.2

### General ISO 5.6.2.1

The laboratory has designed quality control procedures that verify the attainment of the intended quality of results. See:

- LP/PA/HP/SOP118 Cell pathology Internal Quality Control Measures
- LP/PA/CB/OP32 Internal Quality Control Procedures for Clinical Biochemistry
- LP/PA/HA48 Internal Quality Control Procedures for Haematology
- LP/PA/TR62 Blood Transfusion Internal Quality Control
- QP/PA/MB/PRO8 Procedure for Control of Process and Quality Records in Microbiology

### Quality control materials ISO 5.6.2.2

The laboratory aims to use, wherever possible, quality control materials that react in a manner as close as possible to patient samples and spanning the analytical range of methods. Where possible this is independent of the manufacturer of the examination being controlled.

### Quality control data ISO 5.6.2.3

QC results are reviewed and action taken on failures according to departmental SOPs (see 5.6.2.1 above).

Quality control data is reviewed by each discipline and at the Departmental Quality Group meetings to detect trends in examination performance that may indicate problems in the examination system and to enable preventive measures to be put in place. See the minutes of these meetings on Qpulse.

**Quality assessment (Inter-laboratory comparisons) ISO 5.6.3**

**Participation ISO 5.6.3.1**

The laboratory participates in inter-laboratory comparison programmes which are appropriate to the examinations and interpretations of examinations performed by each discipline and, as far as possible, mimic patient samples.

Results are displayed on the EQA notice boards. EQA results are kept in the appropriate file in the laboratory or on the shared drive in the computer, with the current results being on display.

Each discipline has documented procedures for inter-laboratory comparisons:

- QP/PA/MB/PRO1 External Quality Assessment (EQA) Procedure in Microbiology
- LP/PA/HA26 Haematology External Quality Assurance
- LP/PA/TR63 Blood Transfusion External QC/ NEQAS
- LP/PA/CB/OP31 External Quality Assurance Procedures for Clinical Biochemistry
- LP/PA/HP/SOP115 External and Internal Quality Control Slides and the Review System of Reports in Cell Pathology

**Alternative approaches ISO 5.6.3.2**

When an inter-laboratory comparison is not available, the laboratory uses the following approaches to ensure the acceptability of examination results:

- Exchange of samples with other laboratories
- Certified reference materials
- Previously examined samples

**Analysis of inter-laboratory comparison samples ISO 5.6.3.3**

The laboratory integrates inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples using the same personnel and procedures as are used for the examination of patient samples.

The laboratory does not communicate with other participants in the inter-laboratory comparison programme about sample data until after the submission deadline (if at all) and does not refer these samples for confirmation of results, even if this would routinely be done for patient samples.

**Evaluation of laboratory performance ISO 5.6.6.4**

The results of inter-laboratory are reviewed by each discipline at the Departmental Quality Group meetings to detect trends in examination performance that may indicate problems in the examination system and to enable corrective measures to be put in place when pre-determined performance criteria are not met. See the minutes of these meetings on Qpulse

The effectiveness of corrective actions is monitored through regular audit.

**Comparability of examination results ISO 5.6.4**

Where examinations are performed on more than one instrument and/or on more than one site, the laboratory has a documented procedure for comparing equipment and methods to establish the comparability of results. See:

- LP/PA/CB/OP244 Cross Site Internal Quality Control (IQC) Monitoring
- LP/PA/HA48 Internal Quality Control Procedures for Haematology
- LP/PA/TR62 Blood Transfusion Internal Quality Control

## 25. Post examination processes ISO 5.7

Results of laboratory investigations are recorded routinely throughout the day onto the laboratory computer system either automatically following set protocols on the analysers or by the technical and/or clinical staff. Once reports have been verified and validated by the technical or clinical staff they are sent electronically, and where required, printed centrally onto hard copy reports before distribution to the requestor. All clinically significant reports (as identified in the laboratory procedures for clinically significant or critical results) are viewed and validated by the pathology clinical staff. Any changes or additions are entered by the technical staff, under guidance from the medical staff and IT. Results from internal requests are also available electronically on the Trust patient information management system. All of the GP practices served by the department have facilities for electronic result transfer from the pathology system.

**Review of results ISO 5.7.1**

All results are reviewed before release. This may be manually by a member of staff or via defined rules in the laboratory information system. See:

- LP/PA/MB/GEN6 Authorisation using WinPath in Microbiology

- LP/PA/MB/GEN9 Reporting Results in Microbiology
- LP/PA/BHI/IT004 Biochemistry Authorisation
- LP/PA/HA104Criteria for automatic authorisation in haematology
- LP/PA/TR114 Authorisation of results in WinPath Blood Transfusion Module
- CP/PA/CP/SOP6 Pathologist reporting procedure for Cellular Pathology

**Storage, retention and disposal of clinical samples ISO 5.7.2**

This standard is fulfilled by procedures in place in each department for the identification and indexing, security, retention, storage & retrieval and disposal of clinical materials, cited in the relevant procedures for each specimen type. See:

- LP/PA/CB/OP97 Biochemistry control of process and quality records and clinical material
- LP/PA/HA128 Procedure for control of process and quality records and clinical material. Storage within Haematology and Transfusion
- LP/PA/HP/SOP62 Storage, Retention and Disposal in Cellular Pathology
- LP/PA/MB/GEN10 Procedures for the Control of Clinical Material in Microbiology
- QP/PA/GP/EXT001 RCOG Retention and Storage of Pathological Specimens and Records. 5th edition

All routine specimens are stored at appropriate temperatures within the laboratory. Research samples are stored as required by the specific protocol.
Material is retained in line with The Royal College of Pathologists guidelines on the Retention and Storage of Pathological Records and Archives (5th edition 2015) and the Human tissue Act 2004. Human Tissue Act regulations. All sites are licensed to perform scheduled activities

All samples are disposed of in accordance with Trust policy for Waste management POL/NCRM/0004.

## 26. Reporting of results ISO 5.8

Laboratory reports are generated by the Pathology Computer System in a series of queued print runs on a daily basis or may be typed reports by secretarial staff for Mortuary reports (but may also be given by telephone). Each electronic or printed report carries the following information:-

- The laboratory name
- Unequivocal identification of the patient
- Requestor and/or address for delivery
- Specimen type, date and time of collection
- Date and time reported
- Results of the investigation – including reference ranges or interpretative comments as appropriate

- Highlighting of abnormal reports
- Where possible, the ID of person(s) verifying results and authorising release of report
- The status of the report is final unless otherwise stated

Procedures related to the selection, reporting (including telephoned report), reviewing, revising (and the amended report) and release of results and reports (including blood and blood product issue or release of deceased to Funeral Directors) are available within the laboratory procedures and also IT procedures on QPulse.

Clinical staff are available to offer clinical advice and interpretation every day. Each consultant may seek advice from their consultant colleagues or from recognised external experts.

**General ISO 5.8.1**

Result validation is automatic by the laboratory computer system (WinPath) using a rules base, or by manual inspection and review and acceptance of results.
Results of investigations are recorded in real time by the laboratory computer system. Once reports have been validated they are made electronically available to the requestor by iSoft with reports also, as appropriate, printed centrally onto hard copy reports for distribution. The greatest care is taken to ensure that all data recorded onto the Pathology computer system is accurate as verified data will appear on iSoft.

**Report attributes ISO 5.8.2**

Reports are designed to be clear, unambiguous and to contain sufficient information, including interpretive comments, to meet the needs of users. If necessary, the reports contain comments on sample quality if this would compromise examination results and on sample suitability if sample acceptance/rejection criteria are not met.
Electronic results are produced by the department on a real time basis.

**Report content ISO 5.8.3**

Each electronic and paper report carries the following information:-

- Name, hospital number, date of birth, address of patient
- Name and location of the doctor requiring the results
- Sample type
- Clinical details
- Date and time reported
- Results of the tests performed
- Reference ranges, if applicable
- Interpretive comments, if applicable

- If the sample was referred, the name of the reference laboratory producing the result

Processes are in place to ensure that all reports are handled and transmitted confidentially

## 27. Release of results ISO 5.9

### General ISO 5.9.1

When the quality of the primary sample makes it unsuitable for examination or could compromise the result, the report generated by the laboratory makes this clear to the requestor.

Critical i.e. potentially life threatening results are communicated to the requesting location by telephone in accordance with local procedures and RCPath guidelines. Processes are defined in Departmental SOPs:

- LF/PA/MB/FORM134 Reporting of Significant Pathogens and Results in Microbiology
- LP/PA/CB/OP105 Telephone procedure - Clinical Biochemistry
- LP/PA/GP/GR015 Procedure for Giving a Telephoned Report
- LP/PA/HA15 Telephoning of Results Criteria in Haematology
- LP/PA/HP/SOP87 Giving a Telephoned Result in Cellular Pathology
- LP/PA/TR79 Blood Transfusion Telephone Policy

The above procedures ensure that results we are giving via telephone reach only authorised personnel.

### Automated selection and reporting of results ISO 5.9.2

The laboratory LIMS system contains a rules-base that allows automatic reporting of some results. If result is outside of defined rules the reports are allocated automatically to a report queue and are manually checked before report is issued; any pre-analytical or analytical issues that may have affected result are reported and any further action initiated.

### Revised reports ISO 5.9.3

There are policies for amending reports and the subsequent issuing of a revised report described in the relevant department specific SOP's relating to the standard. All electronically generated reports requiring additional, revised or amended data are amended and annotated in accordance with guidance. The WinPath audit trail records all changes to reports. See:

- LP/PA/CB/OP93 Analytical Error handling and amending reports in Biochemistry
- LP/PA/HA127 Amended Reports in Haematology

- LP/PA/MB/GEN9 Reporting results in Microbiology
- LP/PA/TR113 Amended Reports and Results in Transfusion#
- LP/PA/IT002 Procedure for Amending Incorrect WinPath Patient Registrations

## 28. Laboratory Information Management ISO 5.10

The laboratory has access to the data and information needed to provide a service which meets the needs and requirements of the user through Pathology IT system Winpath, Trust Patient Administration System (CAMIS) and request card electronic storage system DART as well as some limited access by authorised individuals to SystemOne for Emergency Department and iSoft (Trust results system) and the electronic patient record system ECDM. As Pathology is part of a larger Trust, the Trust has policies and procedures in place for dealing with Information Management and are generic to all departments. These policies and procedures are available on Staffnet within the Policy and Procedures section and within Commercial Services Documents. Some key documents are:

- Data Protection Act 1998 and disclosure policy POL/HI/0005
- Information Governance Policy POL/HI/0003
- Information Risk Policy POL/HI/0028
- IT Procurement and implementation Policy POL/HIG/0018
- Policy for the testing of information systems POL/HI/0032
- IT Security Policy POL/HI/0002
- Access Control Policy POL/HI/0009
- Clinical Confidential Information Policy POL/HI/0004
- Internet and acceptable use policy POL/HI/0007
- Safehaven Procedure PROC/HI/0002

Other useful documents not within Commercial Services but still within Policies and procedures on Staffnet:

- Freedom of Information Policy POL/CA/0002
- Policy for moving non-electronic records POL/FM/0010
- DSE policy POL/NCRM/0023
- Information Assurance Policy POL/INF/0001

Additional information can also be found within the Information Governance site within Staffnet.

### General ISO 5.10.1

The laboratory has access to a number of computerised systems which includes those integral to the functioning of laboratory equipment, the laboratory LIMS (WinPath), QPulse quality management software and Microsoft Office applications.

New starters have the importance of confidentiality and the Data Protection Act explained to them during the Trust Induction programme and undertake information governance training which is then refreshed annually. See Trust policies POL/HI/IG/0005 Data Protection, POL/HI/IG/0004 Confidentiality and Disclosure Policy and POL/ARC/0007 Information security policy.

The Trust has a Caldicott guardian to ensure that the dissemination of patient information and data is in accordance with national guidelines which include: ensuring security and confidentiality issued by NHS Executive's Security and Data Protection section in February 1999, secure electronic transmission and safe disposal.

The Pathology computer system can only be accessed by staff with a specific user code and password. The level of access is determined according to requirement of the individual job role and set by the Trust IT department. Any maintenance, modification or improvements pertaining to the system can only be done by the IT department. A change control procedure will be followed. Each directorate has a member of staff with specific responsibility for I.T. within their directorate.

Staff have individual logins and are instructed not to leave a computer terminal without logging off first.

The Trust Information and Technology department monitor the access of websites on Trust computers to detect inappropriate activity.

When staff leave the trust Pathology Services are required to undertake an exit process which is covered by Trust policy POL/PD/0028 Leaving Employment Policy. As part of this policy there is a requirement for pathology managers to complete the leaving employment checklist- available on HR management page on staff net.

**Authorities and responsibilities ISO 5.10.2**

The integrity of the LIMS is maintained by the County Durham and Darlington Foundation Trust I.T. department, who are responsible for performing system back-ups and monitoring system performance.

The Laboratory operates a team of IT leads within Pathology. These staff are trained by the service provider to enable day to day functions to be undertaken e.g. creation of new tests, worksheet maintenance and administrative tasks such as IQC set up. The IT leads are responsible for performing testing to an agreed script prior to any system upgrade and verifying performance of the system post upgrade.

The Pathology IT Manager has authority and responsibility for the information system management. The Pathology IT manager and the Trust's IT Department regulate the system (Winpath) security, the system can only be accessed by staff

with a specific unique code and password and the level of access is determined by the Pathology IT manager. Any maintenance, modification or improvements pertaining to the system or discipline specific modules can only be done by the IT manager or delegated individuals within the laboratory and follow a documented change control process requiring testing and verification that changes are as expected.

All users of the LIMS have individual accounts and passwords which are not disclosed to anyone else. Access rights are hierarchical according to department and the ability to validate and authorise results.

**Information system management ISO 5.10.3**

Back up procedures and server monitoring / maintenance is undertaken by the Trust IM&T department on a daily basis. All departments have a contingency plan for loss of the LIMS system which has been tested.

**APPENDIX I**

**Terms and Definitions**

- **Accreditation** - Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.
- **Annual joint review** - Annual review of employee/employer requirements, undertaken to establish mutually acceptable objectives for a defined period of time.
- **Audit -** Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
- **Corrective action -** Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.
- **Department -** Section of a laboratory in which a single pathology discipline pursues its activities.
- **Effectiveness -** Measure of the extent to which planned activities are realised and planned results achieved.
- **Efficiency -** Relationship between the result achieved and the resources used.
- **Examination -** Set of operations having the object of determining the value or characteristics of a property.
- **Laboratory -** Grouping of departments.
- **Laboratory director -** Competent person(s) with responsibility for, and authority over a laboratory
- **Laboratory management -** Those persons who manage the activities of the laboratory headed by the laboratory director.
- **Materials -** consumables, calibrators, reagents, calibration material used in the performance of an examination

- **Multidisciplinary laboratory -** laboratory in which two or more pathology disciplines work in an integrated manner
- **Nonconformity -** non-fulfilment of a requirement
- **Organisation -** Group of people and facilities with an orderly arrangement of responsibilities, authorities and relationships.
- **Organisational structure -** Orderly arrangement of responsibilities, authorities and relationships between people.
- **Post - examination phase (post-analytical phase) -** All processes following the examination including systematic review, formatting and interpretation , authorisation for release, reporting of results, transmission of results and storage of samples of the examination.
- **Pre examination process (pre-analytical phase) -** Steps starting in chronological order from the clinician request, including examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory and ending when the examination procedure starts.
- **Premises -** physical environment in which an organisation carries out particular functions
- **Preventative action -** Action taken to eliminate cause of potential nonconformity or other potentially undesirable situation.
- **Procedure -** Specified way to perform an activity or process.
- **Quality improvement -** Part of a quality management system focused on continually increasing effectiveness and efficiency.
- **Quality management system -** management system to direct and control an organisation with regard to quality
- **Quality manual -** Document describing the quality management system of an organisation.
- **Quality objective -** Something sought, or aimed for, related to quality.
- **Quality planning -** Part of quality management process focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil quality objectives.
- **Quality policy -** Overall intentions and direction of an organisation related to the fulfilment of quality requirements as specified by laboratory management.
- **Record -** Document stating results achieved or providing evidence of activities performed.
- **Referral laboratory -** External laboratory to which a sample is submitted for supplementary or confirmatory examination procedure and report.
- **Remedial action -** *action taken to mitigate the immediate effects of a non-conformity*
- **Requirement -** Need or expectation that is stated, customarily implied or obligatory. **Review -** Activity undertaken to ensure the suitability, adequacy, effectiveness and efficiency of the subject matter to achieve established objectives.
- **Revision -** Introduction of all necessary changes to the substance and presentation of a document to ensure its continuing suitability, adequacy, effectiveness and efficiency to achieve established objectives.

- **Standard Operating Procedure (SOP) -** Defined practical way in which policies are translated into action, a defined way of progressing a course of action or policy
- **User -** Person or organisation using the services of the laboratory. e.g. clinicians, health care bodies, health insurance companies and pharmaceutical companies
- **User dissatisfaction (complaint) -** User opinion of the degree to which the service provided has failed to meet their requirements.
- **User satisfaction -** User opinion of the degree to which the service provided has met their requirements.
- **Validation -** Confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.
- **Verification -** confirmation, through the provision of objective evidence that specified requirements have been fulfilled.
- **Work environment -** Set of conditions under which a person operates.