

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: -

Contents

	ITEM	PAGE
1.	GENERAL INFORMATION	3
1.1	Scope and purpose of this document	3
1.2	Normative Reference and related documents	4
1.3	Responsibility	4
1.4	Terms and definitions	4
1.5	Quality Policy	4
2.	LABORATORY GENERAL INFORMATION & MANAGEMENT REQUIREMENTS	5
2.1	General Laboratory Information	5
2.1.1	Pathology Services	5
2.2	Organisation and Management Structure and Responsibilities	6
2.2.1	Trust Services	6
2.2.2	Pathology Management	7
2.3	Meetings and communications	8
2.4	description and Scope of the Quality Management System (QMS)	9
2.5	Description of the structure and relationships of the documents used within the QMS	10
2.6	Service Agreements	11
2.7	Referral Laboratories, External Services and Supplies & Advisory Services	11
2.8	Complaints & Non-conformities	11
2.9	Continual Improvement, Evaluation & Audit	12
2.10	Control of process and quality records and clinical material	12
2.11	Management Review	13
3.	TECHNICAL REQUIREMENTS	14
3.1	Personnel	14
3.2	Accommodation and Environment	15
3.3	Equipment, Reagents and Consumables	15
3.4	Pre-examination processes	16
3.5	Exam processes and ensuring Quality of examination results	16
3.6	Post-examination processes and reporting & release of results	17
3.7	Laboratory Information Management	18
	APPENDIX I – Terms & Definitions	20
	APPENDIX II – Clinical Specialist Services Organogram November 2017	22

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 but also appendices specific to the Departmental disciplines. Information regarding the distribution and review history of this document can be found in the document control system.

1.1. 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 (in brackets) and to procedures (indicated by square brackets **[in bold]** and will be **blue** where Trust documentation and black where local Pathology documents) 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. Reference is made to procedures used in the parent organisation, but do not form part of the controlled documentation of the Pathology Quality Management System but can be found on the Trust Intranet site under policies (circled in red on picture 1.).

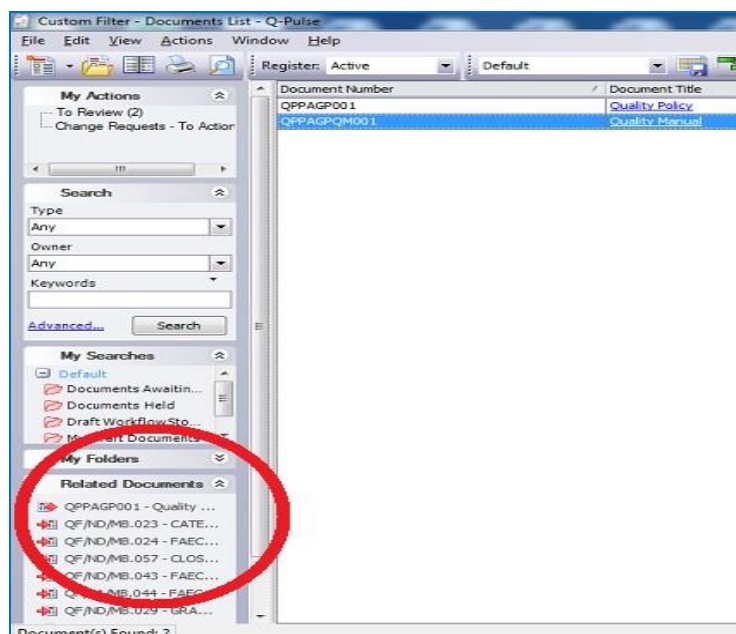
Picture 1.



1.2. 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](#))
- Any related documents are linked to this document through the QPulse (Gael Quality UK) related documents section (circled in red on Picture 2)



Picture 2. QPulse page

1.3. 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. 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.

1.4. Terms and definitions

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

1.5 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 & MANAGEMENT REQUIREMENTS

2.1. General Laboratory Information

A single Pathology service covers the Trust and there are main laboratories on the acute sites of Darlington & Durham. 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	Darlington Memorial Hospital
North Road,	Hollyhurst Road
Durham	Darlington
DH1 5TW	DL3 6HX

2.1.1 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. In addition the laboratory also provides District Cervical Cytology screening services. The Clinical Biochemistry, Haematology and Blood Transfusion offer a 24 hour laboratory service and a Microbiology service is provided 24 hours with an on-call service available outside normal working hours. The service is Consultant led in each discipline. The departments currently have more than 200 staff, including consultants.

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.

2.2 Organisation and Management Structure and Responsibilities

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

2.2.1 Trust Services

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

There are five Clinical Care Groups:

- Acute & Emergency Care Group
- Surgery Care Group
- Integrated Adult Care Group
- Family Health Care Group
- ***Clinical Specialist Service Care Group***

There are also Corporate Directorates:

- Assurance, Risk & Compliance
- Commercial Services
- Estates and Facilities
- Finance / Chief Operating Officer
- Human Resources and Organisational Development
- Medical Director
- Service Transformation

Pathology sits within the Clinical Specialist Services Care Group. The diagram in Appendix II 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]

Cytology Structure – [LF/ND/CP/HR6]

Microbiology Structure – [LF/PA/MB/FORM1]

2.2.2. Pathology Management

Pathology is directed by a Clinical Director who reports to the Care Group Clinical 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.

Pathology is divided into:

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

Pathology has a General Manager (Grade 8b) who report 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 **Clinical Director** 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.
- **Pathology Management** 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.
- The **Quality Manager** 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.

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.

2.3 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

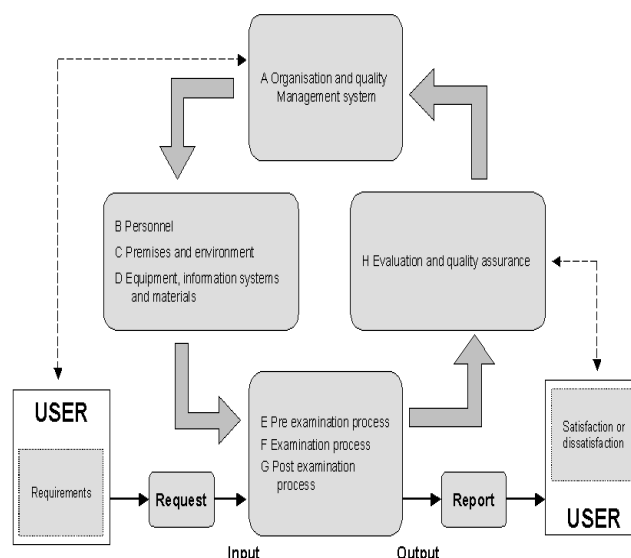
meetings, senior meetings, joint laboratory meetings (Cell Sciences/Blood Sciences) etc.

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.

The needs of the users are kept under constant review. These are ascertained by regular contact with all users of the service both informally and formally via the Pathology Newsletter. User questionnaires and user group meetings are also used. They 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.

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

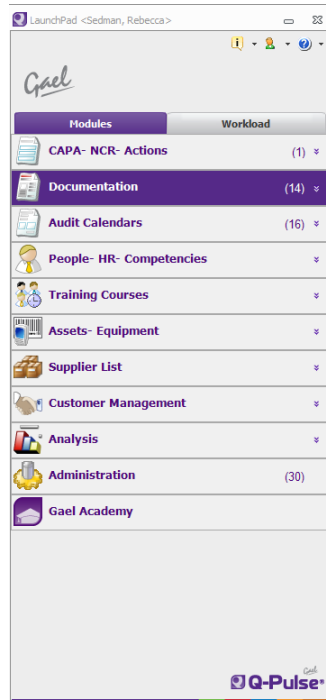
The QMS for Pathology is a set of co-ordinated activities to direct and control the department in order to continually improve the effectiveness and efficiency of its performance. Pathology runs the quality management system (QMS) as a vehicle to deliver a quality service. The QMS defines the organisational 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. Pathology uses a process and systems approach and this is demonstrated with the diagram on below.



Picture 4. Diagram of the Qms FOR Pathology, CDDFT.

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.

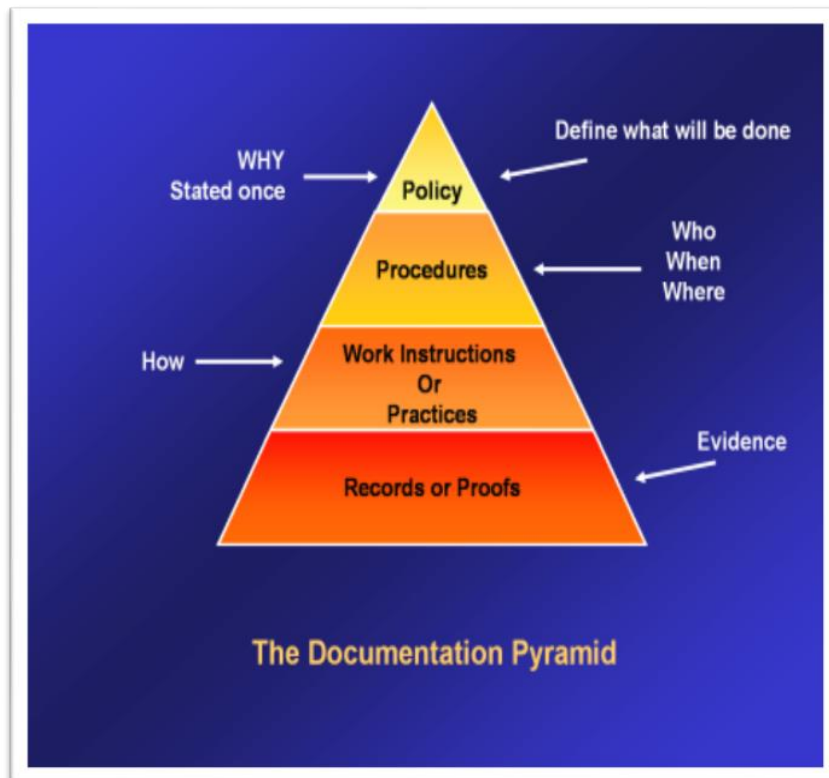


Picture 5. QPulse menu

2.5 Description of the structure and relationships of the documents used within the QMS

The documents used within the QMS are Policies, Procedures (Standard Operating Procedures), working instructions (templates, posters, flow diagrams etc) and records (monitoring charts such as freezer charts, QC charts, NEQAS reports, non-conformity records, meeting minutes etc). Some of these will be owned by External Bodies or the Trust (i.e. ISO Standards Document, Human Resource Policy) and only referred to within other policies or procedures and others will be owned by Pathology. All Pathology documents will be held within QPulse as well as an additional hardcopy where appropriate (the location will be documented in QPulse), all external or Trust documents required for the QMS will be documented onto the QPulse system although the actual document may not be physically stored on the system. The document control procedure **[QP/PA/GP/002]** is available on QPulse and describes how the documents are identified, used and stored through a document control procedure and relates to the Trust *Policy for the Development of Procedural Governance Documents* **[Corporate/POL/0001]** and the Trust *Corporate Records Management Policy* **[POL/CA/0005]**.

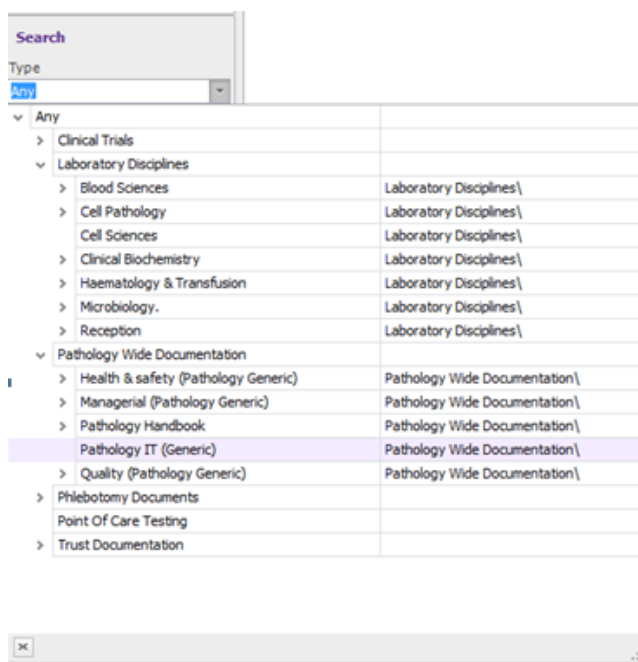
Every policy should have 1 or more procedures related to it to ensure the policy can be effectively and efficiently delivered (appropriate linked training) and this will be documented through a number of records. Therefore there should be fewer policies than procedures and fewer procedures than records as can be demonstrated with the documentation pyramid below.



Picture 6. Documentation pyramid

The documents are identified into categories and stored on QPulse within that categories as can be seen in the screen grab below. The main document categories within Pathology are:

- **Generic to all disciplines** - External documents, Health & Safety, IT, Quality, Managerial, Pathology Handbook, Training, Transport
- **Specific to departments** – Clinical Trials, Point of Care Testing, Laboratory Documents



Picture 7. Qpulse document types

2.6 Service Agreements

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.

2.7 Referral Laboratories, External Services and Supplies & Advisory Services

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* [\[MP/PA/GP/REF001\]](#)

2.8 Complaints & Non-conformities

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.

2.9 Continual Improvement, Evaluation & Audit

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:

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

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.

2.10 Control of process and quality records and clinical material

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.

2.11 Management Review

The Laboratory management team via the DOP conduct an annual review which considers the following items of information:

- Periodic review of requests and the suitability of procedures and samples requirements
- Assessment of user feedback
- Staff suggestions
- Internal audits
- Risk management
- Use of quality indicators (key performance indicators – KPIs and Quality Indicators - QI)
- Reviews by external organisations and parties (Accreditation, licencing and other investigation bodies)
- Results of the participation in inter-laboratory comparison programmes (i.e. EQA – NEQAS WEQAS, Keele benchmarking etc)
- Review of complaints monitoring and resolution
- Supplier performance review
- Identification and control of non-conformities
- Continual improvement results (including CA/PA)
- Review of previous management review and any follow-up actions
- Review of any changes in volume/scope of work, personnel, premises or other that could affect the QMS
- Recommendations for improvement, including technical requirements

Records are kept and key objectives for subsequent years defined and plans formulated for their implementation. The records are kept with the Lead BMS 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.

3. TECHNICAL REQUIREMENTS

3.1 Personnel

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.

Picture 8.



These documents include:

- *Recruitment Selection procedure* [[PROC/PD/0003](#)]
- *Employment Checks* [[PROC/PD/0025](#)]
- *Management of Employee personal file information* [[POL/PD/0025](#)]
- *Induction* [[POL/PD/0051](#)]
- *Education, Learning, Development (study leave) policy* [[POL/PD/0008](#)]
- *Appraisal* [[POL/PD/013](#)]
- *Training needs analysis monitoring & Evaluation* [[POL/PD/0053](#)]
- *Staff communications* [[POL/PD/0018](#)]
- *Working time regulations* [[POL/PD/019](#)]
- *Disciplinary Procedure* [[PROC/PD/009](#)]

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.

3.2 Accommodation and Environment

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 Trustwide Estates and Facilities procedures and policies available on the Staffnet site within the Policies and Procedures Section.

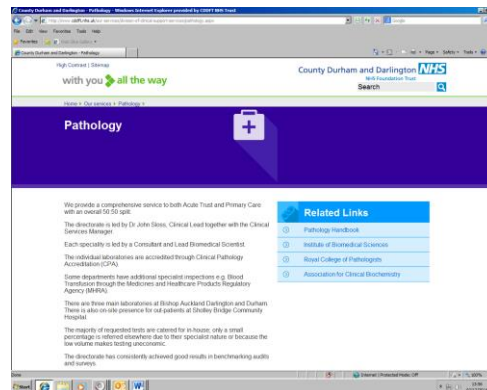
3.3 Equipment, Reagents and Consumables

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.

3.4 Pre-examination processes

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)



Picture 10.

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

3.5 Exam processes and ensuring Quality of examination results

The range of examinations offered by a department is designed to ensure that a first class service is offered to our users. The range of tests available is constantly reviewed by the departments and is discussed at departmental meetings. 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.

3.6 Post-examination processes and reporting & release of results

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.

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.

3.7 Laboratory Information Management

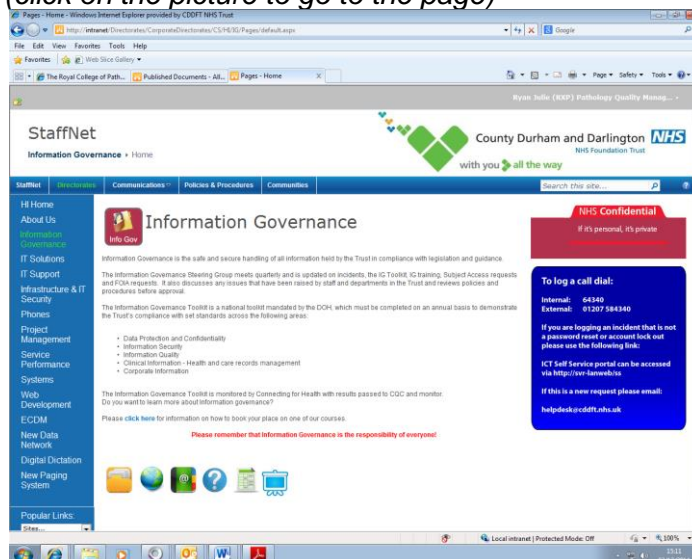
The laboratory has access to the data and information needed to provide a service which meets the needs and requirements of the user through Pathology IT system Winpath, Trust Patient Administration System (CAMIS) and request card electronic storage system DART as well as some limited access by authorised 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](#)]
- *Saf haven 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. *(click on the picture to go to the page)*



Picture 11.

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.

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.

APPENDIX II



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See individual Departmental Specific charts (identified on page 6) for each Pathology Discipline and named individuals.