Countess of Chester Hospital NHS Foundation Trust

PATHOLOGY QUALITY MANUAL

- This document, together with the processes and procedures specified in this manual and in the sub-section manuals, represent the quality management system of the Pathology Laboratory of the Countess of Chester Hospital NHS Foundation Trust

- It has been compiled to meet the requirements of the international standard **Medical Laboratories – Requirements for quality and competence (ISO 15189:2012)** and other appropriate national and international standards and any regulatory requirements

- The Pathology Laboratory (Clinical Biochemistry/ Haematology and Blood Transfusion/ Cellular Pathology/ Mortuary/ Immunology and Phlebotomy) CN9061 is accredited by UKAS to ISO 15189:2012 until January 2023.
  Our accreditation is limited to those activities described on our UKAS schedule of accreditation found here.

  https://www.ukas.com/

- All processes and procedures specified herein are mandatory within the Pathology Laboratory.

- Information regarding the distribution and review history of this document can be found in the document control system (Q Pulse).

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0 General Information

The Countess of Chester Hospital NHS Foundation Trust consists of a 600 bedded large district General Hospital, which provides its services on the Countess of Chester Health Park, and a 64 bedded Intermediate Care Service at Ellesmere Port Hospital. The Trust has almost 4,000 staff and provides a range of medical services to more than 445,000 patients per year from an area covering Western Cheshire, Ellesmere Port, Neston and North Wales.

Legal Entity:

The Countess of Chester Hospital National Health Service Trust (Establishment) Order 1992
https://www.legislation.gov.uk/uksi/1992/2463/contents/made

The Pathology Directorate is part of the Division of Diagnostics and Infrastructure. It is located in the general wing of the main Countess of Chester Hospital site.

There are three departments within the pathology directorate: Blood Sciences, Cellular Pathology, and Microbiology.

Blood Sciences comprises the disciplines of Clinical Chemistry, Haematology and Blood Transfusion and Immunology. Point of Care Testing (POCT) within the Trust is overseen by the Clinical Consultant Biochemist and a senior BMS (see Appendix Four).

Cellular Pathology comprises the disciplines of Histopathology, Diagnostic Cytology and Anatomical Pathology.

The Chester and Wirral Microbiology Service (CWMS) is part of the collaboration between the Countess of Chester Hospital NHS Foundation Trust and Wirral University Teaching Hospital NHS Foundation Trust (WUTHNFT). The laboratory and staff is managed by WUTHNFT. Two of the Medical Microbiology consultants are employed and managed by the Countess of Chester Hospital NHS Foundation Trust.

The postal address is:-	Directorate of Pathology Countess of Chester Health Park Liverpool Road Chester Cheshire CH2 1UL	Tel 01244 365000

1 Quality Policy

The Quality Policy of the Directorate of Pathology, Countess of Chester Hospital NHS Foundation Trust

The Directorate of Pathology comprises several departments providing discipline-specific services:

- Microbiology and Serology laboratory services are provided by **Chester & Wirral Microbiology Service** (collaborative service with Wirral University Hospitals NHS Foundation Trust) and clinical Microbiology services by the **Microbiology** department.
- Histology, Cytology and Mortuary Facilities are provided by the **Cellular Pathology Department.**
- Chemical Pathology, Haematology, Anticoagulation and Blood Transfusion are provided by the **Blood Sciences Department.**
- Immunology and Allergy testing is provided by the **Immunology Department.**

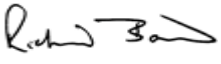
SAFE, KIND, EFFECTIVE. We take pride in delivering to all our users a quality clinical service that meets the highest standards of professional performance, founded on the Countess of Chester Hospital NHS Foundation Trust Behavioural Standards of Leading People in Working Together with Respect and Fairness and a Positive Attitude to continuously work towards Achieving Excellence.

We will achieve this through a **patient-centered approach,** and in striving to **improve** our service by:

- Operating a quality management system to integrate the organisation, procedures, processes and resources.
- Setting and reviewing quality objectives and plans in order to implement this quality policy.
- Ensuring that all personnel are familiar with this quality policy, the quality manual and all relevant procedures to ensure a quality service at every stage of the patient journey.
- Committing to providing a safe environment for the health, safety and welfare of all its staff and extending this to all visitors to the departments. Both staff and visitors will be treated with respect and dignity at all times
- Upholding the Countess of Chester Hospital NHS Foundation Trust Values and Behaviours, professional values, and committing to good professional practice and conduct.

The Directorate of Pathology will comply with all relevant regulations and legislation covering its activities, including environmental legislation. It is committed to continuing compliance with relevant standards set by the United Kingdom Accreditation Service (UKAS), Human Tissue Authority (HTA) and the Medicines and Healthcare products Regulatory Authority (MHRA) and will ensure:

- The recruitment, training, development and retention of highly qualified, motivated and caring staff at all levels.
- The proper procurement and maintenance of equipment and other resources required for the provision of the Service.
- The proper handling of all specimens, so as to ensure the correct performance of laboratory examinations. Examination and quality assurance procedures used will ensure the highest achievable quality of test results and deliver the service we would expect to receive ourselves.
- The reporting of results of examinations in a timely, confidential, accurate and clinically useful manner.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to identify opportunities for continual quality improvement.



The Divisional Director Pathology: Richard Baird. 12/01/23

2 Definitions

This Quality Manual fulfils two functions. It describes the Quality Management System for the benefit of the laboratories own management and staff, and it provides information for users and for inspection/accreditation bodies. Throughout the text there are references to the ISO15189:2012 standard (in brackets) and to procedures [indicated by square brackets], 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. The sections of the Quality Manual are arranged so that they equate to the requirements of the international standard **Medical Laboratories – Requirements for quality and competence (ISO 15189:2012)**.

Standard abbreviations used in this document:

BMS	Biomedical Scientist
BSW	Biomedical Support Worker
UKAS	United Kingdom Accreditation Service
DA	Divisional Accountant
HEI	Higher Educational Institute
HTA	Human Tissue Authority
MHRA	Medicines and Healthcare Products Regulatory Agency
MSDS	Manufacturer's safety data sheets
QMS	Quality management system
R&PSL	Risk and Patient Safety Lead
SOP	Standard Operating Procedure

3 Organisational Overview, Responsibilities and Authorities

The Trust is managed by a Board of 12 members. The Board meets monthly to consider all aspects of health care organisation, management and the overall strategic direction of the Trust. It holds four meetings per year in public.

The Board is headed up by a Non-Executive Chairman, appointed by the Board of Governors. It includes five Non-Executive Directors and six Executive Directors. The Non-Executive Directors are appointed, again by the Board of Governors, on the basis of their wide experience in the community and the insights they bring from other professional areas.
The Executive Directors are all experienced health professionals. In addition to the Board of Directors meetings there is a Management Board chaired by the Chief Executive comprising Executive Directors, Divisional Directors, Divisional Medical Directors, Clinical Directors and the Chairman of the Medical Staff Committee. It meets monthly to deal with the bulk of the day to day business, reporting formally to the Board of Directors.

The Countess of Chester Hospital NHS Foundation Trust is the legal entity responsible for the activities of the laboratory and its staff. (4.1.1.2)

The staff of the laboratory are bound by the following Trust policies and structures in regard to their ethical conduct (4.1.1.3):

Trust standing financial instructions

http://doclib.xcoch.nhs.uk/Documents/COCH%20FT%20Standing%20Financial%20Instructions.docx

Human Tissue Act – the Trust holds an HTA license (no 12049). Jane Tomkinson is the Corporate License Holder, Mr Alan Shaw (Cellular Pathology Manager) is the Designated Individual for post-mortem activities, and Peter Bamford is the person designated for research activities. Mr Robin Mealing is person designated for the Mortuary.

Patient confidentiality – the Trust Caldicott guardian is the Executive Medical Director. The Trust has an information governance team in place that provides leadership and advice to all staff. The following committees are in place to oversee governance issues:

- Information Governance Steering Group
- Information Governance Operational Group
- Information Security Group
- Data Quality Group

The management structure of the Trust is shown in the diagram below:


Jane Tomkinson
Acting Chief Executive
Ian Haythornthwaite
Chairman
Nigel Scawn
Executive Medical Director
Hilda Gwilliams MBE
Director of Nursing & Quality
Nicola Price
Director of People and Organisation Development
Alison Lee
Managing Director of Integrated Care Partnership
Cathy Chadwick
Chief Operating Officer
Simon Holden
Chief Finance Officer/ Deputy CE
Cara Williams
Chief Digital Information Officer

3.1 Relationship to the Countess of Chester Hospital NHS Foundation Trust

In common with many other Trusts there is a well-developed divisional model, each of which is headed by an executive director. Cathy Chadwick, Chief Operating Officer, is the executive lead for the division of Diagnostic & Infrastructure. Each division may have within it a number of directorates. The division of Diagnostic & Infrastructure includes the directorates of:

- Pathology.
- Radiology.
- Pharmacy.
- Facilities
- Estates
- Health Records
- Outpatients

The organisational relationship of the Diagnostic and Infrastructure Division within the Trust is shown below:

Divisional structure (as of December 2022) [DOC2531]

DOC2531 DPS - Structure 2023.docx

3.2 Organisation and responsibilities within the Pathology laboratory

Each departmental manager is professionally responsible to the Consultant Head of their particular department. The consultant heads of department, with each Departmental Laboratory Managers, are directly accountable to the Divisional clinical director for the division.

Each department within Pathology comprises a team of biomedical scientists (BMSs), Biomedical Support Workers (BSW) and secretarial/clerical staff performing duties in their own specific areas. Departmental organisational charts are given in Appendix Two.

Roles and responsibilities within the Pathology Directorate

Laboratory Director Role (or designates for the delegated duties)/Consultant Head of Department.

The Laboratory Director role (delegated duties performed by designates in Pathology) provides leadership and functions as a member of the Pathology team, to provide clinical, scientific, professional, consultative, advisory, organisational, administrative and educational direction for the laboratory services. The duties are defined in [DOC44 – Laboratory Director Role Duties], which include a table of designates for the delegated duties.

Each Consultant Head of Department is accountable to the Divisional Medical Director. For the reporting structure see [DOC2531]. They are responsible for leadership, communication and team working within the

laboratory. This includes accountability for all aspects of clinical governance. They provide professional direction for each department and are available for clinical advice for users. The Consultant Head of department work with the Laboratory Manager to deliver a compliant, high quality and cost-effective service. [DOC2532]

Monthly 1:1 meetings are held between the Divisional Director and the Laboratory Managers, and the Consultant Head of Departments in addition to the meetings listed in the Information and Systems section below.

Laboratory manager (Band 8a/b/c)

Each Laboratory Manager is responsible for the operational management of their department within the Pathology Directorate. The Laboratory Manager works with the Clinical Lead to develop and implement the planning and performance management agenda. The Laboratory Manager provides operational management leadership to the department to ensure effective budget management and monitoring, workforce management and planning and ensuring effective use of resources and equipment. The Laboratory Manager plays a lead role in modernisation of the service in line with local and National strategies.

The position has a lead role in managerial, educational, professional and technical issues within the department/discipline, in conjunction with the Clinical Head of the department. This includes:

- Responsibility for the Technical development of the service in close collaboration with the Clinical Head of the Department.
- Development and promotion of Directorate wide working and standardization of operational policies, procedures and practices within the discipline and within the Pathology Directorate Management team.
- Contributing to the Pathology Directorate Management team to develop and implement the planning and performance management agenda for Pathology.
- Overall responsibility for ensuring that UKAS ISO 1589:2012 Accreditation compliance is maintained in their department.
- To be the departmental Safety Officer to ensure, in liaison with the Directorate safety officer and Directorate risk manager, a safe environment by maintaining adequate levels of safety and security within the laboratory according to Trust and Laboratory policies and procedures.

The laboratory manager's duties are defined in the job descriptions [BSLABMAN – Blood Sciences Lab Manager] and [CPMANAGER– Cellular Pathology Lab Manager]

The Quality Manager

The Quality Manager ensures, on behalf of the Laboratory Management, that the Directorate's Quality Management System functions correctly.

The Quality Manager has a defined role for:

- Ensuring that a Quality Management System is implemented and maintained.
- Overall control of quality and advising and monitoring all aspects of quality within the Directorate.
- Arranging document control and maintenance.
- Planning and organising audits and reviews.
- Ensuring that details of reviews are recorded.
- Ensuring the completion and discharge in the appropriate timescale of corrective actions resulting from audits.

- Reporting to Laboratory Management on the functioning and effectiveness of the Quality Management System.
- Co-coordinating the awareness of the needs and requirements of the users.

The quality manager's duties are defined in [PATHQUALMAN – Pathology Quality Manager]

The key managerial and technical personnel are supported by staff that will deputise for them in their absence to ensure continuity of the service. These deputy responsibilities are outlined in the table below:

Key Pathology Staff	Deputy Managerial Responsibilities	Deputy Technical Responsibilities
Director Blood Sciences	Deputy Director of Blood Sciences	Haematology Clinical Lead
Pathology Services Manager Health & Safety Officer	Blood Sciences Operational Manager/ Cellular Pathology Laboratory Manager/ Transfusion Manager	Band 7 Blood Sciences BMS
Blood Sciences Operational Manager	Pathology Services Manager/ Transfusion Manager	Band 7 Blood Sciences BMS
Transfusion Manager	Pathology Services Manager/ Blood Sciences Operational Manager	Band 7 BMSs - Transfusion
Immunology Service Lead	Pathology Services Manager/Blood Sciences Operational Manager	Immunology BMS staff/ Consultant Clinical Biochemist
Director of Cellular Pathology	Consultant Histopathologist of the week	Consultant Histopathologist
Cellular Pathology Laboratory Manager Health & Safety Officer	Pathology Services Manager/ Quality Manager	Band 7 BMSs- Cellular Pathology
Quality Manager	Cellular Pathology Laboratory Manager	Quality leads for Cellular Pathology/Blood Sciences Pathology Band 7 BMSs

Information and Systems Management

This is a shared role with the Trust IMT department. A senior IT applications specialist and a Pathology Band 7 IT specialist have been appointed to:

- To act as Directorate/Pathology Lead for Trust wide Information Technology.
- To be responsible for the IT development of the service and direct assessment of new software and hardware for the provision of effective IT solutions for the Trust wide Pathology service.
- To manage the Trust wide and GP electronic reporting system.

The management of the directorate is facilitated by the programme of regular business meetings which take place within the directorate. These are listed in the following table:

Directorate Level Meetings			
Title:	**Chair:**	**Frequency:**	**Topics covered:**
Management Review (4.15)	Quality Manager	Annual	Full review of all services
Pathology Quality Group	Quality Manager	Bi-monthly	Quality Management issues for Pathology
Directorate Group (4.1) (Consultants, Managers, CFA, R&PSL. HR, IT analyst)	Dr N Meara	Bi-monthly	Wide range of issues affecting Pathology: includes governance, finance, quality report, performance management etc.
Senior Managers Group (4.1)	Managers on rotation	Monthly	Pathology management operational issues, incident review, health & safety, IT issues
Pathology Governance Group (4.1)	Director of Blood Sciences	Monthly	Risk register, incident review, compliance with Trust/national policies, business continuity

In addition the departments hold their own monthly business meetings to discuss issues relating to their own disciplines.

PATHOLOGY DEPARTMENT MEETINGS

Title	**Chair**	**Frequency**
Hospital Transfusion Team Meeting	Consultant Clinical Lead	Monthly
Hospital Transfusion Committee Meeting	Consultant Clinical Lead	X2 Yearly
Blood Sciences Management Meeting	Blood Sciences Manager	Bi-monthly
Blood Sciences Operational Meeting	Consultant Clinical Lead	Monthly
Blood Sciences Clinical Team Meeting (COCH and WUTH)	Consultant Clinical Lead	Monthly
Blood Sciences Staff meeting	Blood Sciences Manager	Monthly
Haematology Consultant Meeting	Consultant Clinical Lead	Bi-monthly
POCT Operational Meeting	Clinical Biochemist	Monthly
Immunology Meeting	Consultant Clinical	Bi- Monthly

	Biochemist	
Cellular Pathology Senior Staff Meeting	Cellular Pathology Manager	Monthly
Cellular Pathology Staff Meeting	Cellular Pathology Manager	Scheduled as required

4 Management Requirements

4.1 Organisation and management responsibility

Laboratory Management is committed to the development, implementation and continual improvement of its quality management system (QMS). This requirement is achieved by:

4.1.2.1 Management Commitment

The organisation and management of the pathology laboratory is detailed in section 3 of this quality manual. [DOC255 – Cellular Pathology Structure] [PATHINFO034- Blood Sciences Structure] [DOC2531- Diagnostics & Infrastructure Division]

Laboratory management ensures that there is no involvement in any activities that could diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity. All of the activities undertaken are free from any undue commercial, financial or other pressures and influences that could adversely affect the quality of work produced. Laboratory management ensures compliance with current national legislation and regulations in relation to ethical conduct according to COCH policies found on the intranet site. In respect of procurement the COCH standing financial instructions apply.

4.1.2.2 Needs of users

The directorate of pathology obtains feedback from GPs and hospital doctors through questionnaires seeking information on user satisfaction, suggestions for improvement of the service and the Datix reporting system. Feedback from our users is discussed within the directorate and, where possible, alterations and improvements to our service were put into place.

The needs of the users are identified through audits of customers' requirements, satisfaction surveys, review of complaints [QMS016] - Assessment of user satisfaction, Complaints and Compliments and clinical incidents [QMS013] - QMS Identification and control of non-conformities. Assessment of user satisfaction and complaints is reported on a regular basis to the governance and directorate management committees. Consideration of the findings form part of the annual management review (4.1.2.1g). The Pathology management team has input into the Diagnostics Review Group hosted by Clinical Commissioning Group.
All formal agreements to provide medical laboratory services between the laboratory and its users are documented. This document ensures that the users' requirements are adequately defined, documented and understood, the laboratory has the capability and resources to meet these requirements and users are informed of any deviation from the agreement. All aspects of the document should be reviewed and when the agreement needs amending all amendments are communicated to all affected parties. [PATHOL006] - Guidance on setting up SLA's with external agencies/users.
The needs of service users are assessed through audit meetings, service questionnaires and feedback from Clinicians via Multi-Disciplinary Team (MDT) meetings. These are translated into requirements that give focus to objective setting and planning within the QMS.

Where service level agreements are in place, these are agreed by both parties and reviewed regularly (4.4.2).

4.1.2.3 The quality policy of the laboratory is reviewed annually and issued to all staff via Q Pulse. A copy is also placed on the Trust intranet and within the laboratory handbook.

4.1.2.4 As part of the business planning process, the department sets its quality objectives with consultation with the rest of the directorate and division. The senior management committee is responsible for ensuring that plans are made to meet these objectives. The annual management review determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans and the functioning of the quality management system**.** Progress on the quality and service improvement plan is monitored at least quarterly at the senior managers meetings.

4.1.2.5 Responsibilities, authority and interrelationships are defined in the various organisational charts and job descriptions of key personnel (see section 3 of this manual).

4.1.2.6 Communication between management and staff is conducted in various ways:-

- Regular minuted staff meetings
- Email and action notices
- Q Pulse quality management software
- Staff noticeboards
- Annual appraisals and 1:1 meetings

4.1.2.7 The quality manager is responsible for ensuring the quality system is implemented and maintained across all departments, and for reporting its functioning and effectiveness to laboratory management. Co-ordinating awareness of the needs and requirements of users is also a key responsibility. The roles and responsibilities are fully defined in the job description [PATHQUALMAN]. The pathology quality manager meets regularly with the senior management committee, pathology governance committee and the directorate committee to give feed-back and ensure the proper running of the quality management system.

4.2 Quality Management System

4.2.1 The laboratory has a well-established quality management system (QMS) that fulfils the requirements of the international standard ISO 15189:2012. Documentation relating to the QMS is managed via Q Pulse software.

4.2.2.1 The QMS includes:

- A quality policy [PATH QUAL POLICY]
- Quality objectives (set annually) [DOC5743 Quality Improvement Plan 2023]
- Pathology Service Objectives (set annually) [DOC5744 Quality Service Objectives 2023]
- This quality manual [QMS007]
- Standard operating procedures and policies
- Documents, process records, quality records, inventories of equipment, reagents, MSDS, kit inserts
- Copies of applicable regulations, standards, advice form external agencies

4.2.2.2 This standard is fulfilled by the production of this quality manual.

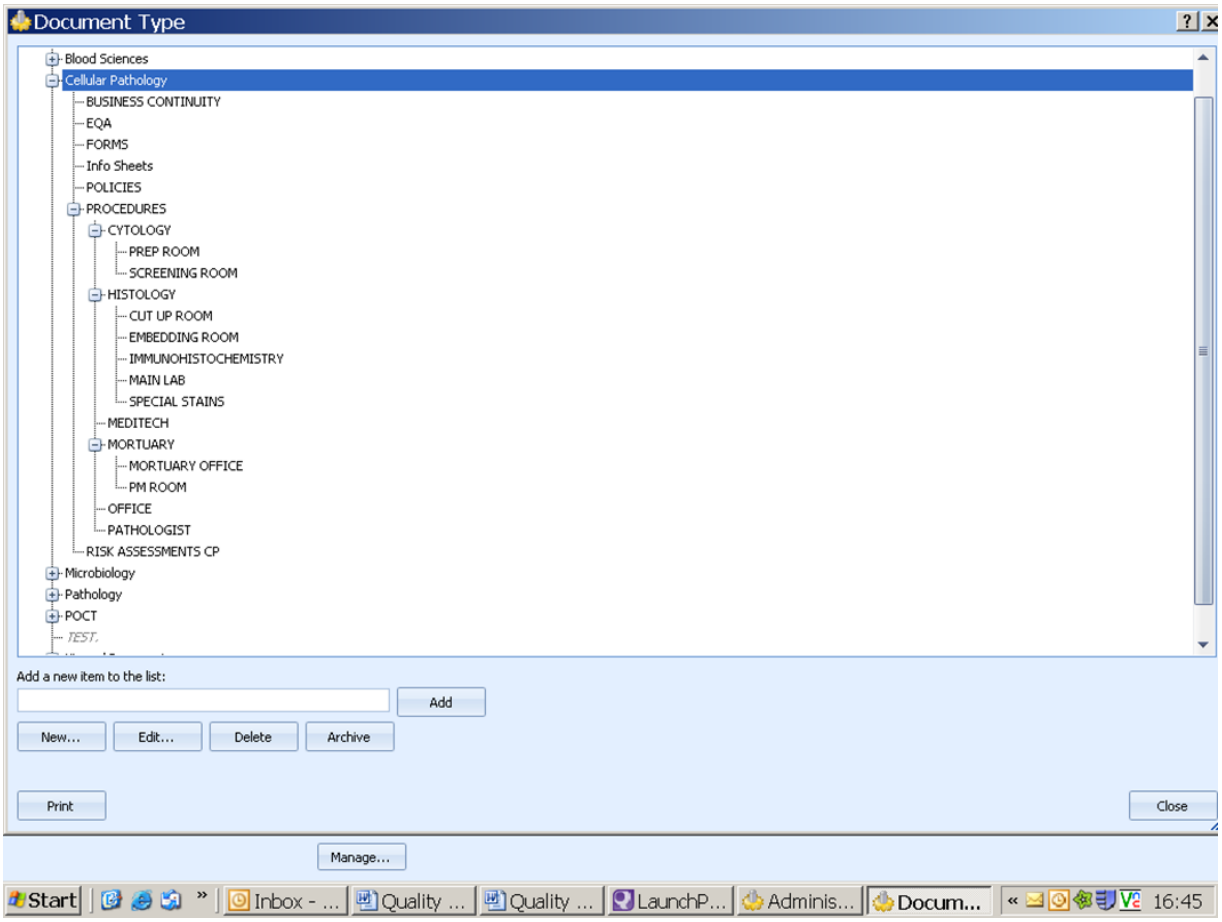
4.3 Document control

This standard is fulfilled by procedure [QMS001 - Document Control], (4.3).

Structure of Documentation used in the quality management system

The lists of current pathology-wide and departmental policies, procedures and forms can be viewed and accessed via Q-Pulse. The system is available to all laboratory staff throughout the directorate. A printed copy of each SOP may also be available in the relevant laboratory areas.

The screen shot from Q-Pulse on the following page shows how the document types are structured and accessed for the Cellular Pathology department. This structure is mirrored in each department in Pathology. This consists of department wide documents such as business continuity plans, EQA reports, forms, information sheets and policies, then procedures (SOPs) for each area of the laboratory and finally risk assessments.



4.4 Service agreements

The department currently has service level agreements with a variety of other departments, hospitals and institutions. All information related to these agreements are held on Q Pulse or with individual managers if in development/review.

The laboratory has a policy [PATHPOL006 – guidance on setting up SLAs with external services users] which describes best practice in setting up and reviewing SLAs.

4.5 Examination by referral departments

4.5.1 The laboratory has a policy [PATHSOP859 Referral to other laboratories – a general overview] which describes the procedure for selection and evaluation of referral laboratories and external consultants.

4.5.2 The laboratory is responsible for passing on the results/reports from external bodies to the end user. This is described in [PATHSOP859 Referral to other laboratories – a general overview] [BS-SOP003 – Reporting Send away Results] and [CPOFF15 – Addendum Reports]

4.6 External services and supplies

The laboratory has policies [PATH024 Equipment – management and procurement] [PATH025 Management of reagents, calibration and control materials]

4.7 Advisory services

Laboratory consultant staff are available to give advice to users and clinicians in person or by telephone or via email.

4.8 Resolution of complaints

The laboratory has a policy [QMS016 – Complaints and user satisfaction] which describes the roles and responsibilities of laboratory staff in handling complaints and user feedback.

4.9 Identification and control of non-conformities

The laboratory has a policy [QMS013- QMS Identification and control of non-conformities] which describes the procedures for dealing with non-conformities in the laboratory.

4.10 Corrective action

The laboratory has a policy on internal audit [QMS004 Audit] which describes the processes involved in taking corrective action to eliminate causes of non-conformities.

4.11 Preventive action

The laboratory has a policy on internal audit [QMS004 Audit] which describes the processes involved in taking preventive action to eliminate potential causes of non-conformities.

4.12 Continual improvement

The laboratory has a policy on continual improvement [QMS015- Quality Improvement].

4.13 Control of records

The laboratory has a policy [QMS001 Document control] which describes the procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of all quality and technical records.

4.14 Evaluation and audits

4.14.1 The laboratory has a policy on internal audit [QMS004 Audit] which describes the processes involved in evaluating and monitoring the pre-examination, examination and post-examination processes as well as the effectiveness of the quality management system

4.14.2 The repertoire of tests available (including instructions for sample volumes, collection device and preservative requirements) is scrutinised as part of the regular laboratory handbook review. Changes to the repertoire may occur when new tests or instrumentation are introduced and is captured via regular management meetings as a standard agenda item. Certain requests are vetted by consultant staff to ensure that the test(s) requested are clinically appropriate.
The department managers and clinical leads will perform the review of the Laboratory repertoire of tests annually [DOC 2048]
The Schedule of Accreditation details the tests/methods that conform with the ISO 1589:2012 –Medical Laboratory standards as accredited by UKAS [DOC 2998]
New tests and methods are introduced on a planned basis through Change Control [QMS003] following suggestions from staff, requests by users, recommendations from external bodies or the introduction of new instrumentation.

4.14.3 The laboratory conducts a formal user survey on a regular basis (usually once every three years). Feedback from users in the form of suggestions, complaints or requests for new tests is taken to the appropriate departmental meetings for discussion.

4.14.4 Staff suggestions are welcomed. Staff suggestion boxes/noticeboards are provided in the department and any ideas put forward are discussed and recorded at regular staff meetings. Staff suggestions are recorded on Q Pulse as quality improvements in the CAPA module.

4.14.5 The laboratory has a planned programme of internal audits which are managed via the Q Pulse system. This is described in [QMS004 Audit]

4.14.6 Staff in the Pathology department, have access to the Trust Intranet where the Datix system for clinical and non-clinical incident reporting is held. This process is described in [QMS005-Incident Reporting].

4.14.7 Quality Indicators are employed by Pathology to monitor and evaluate the performance of Pre-examination, examination and Post-examination processes. This process is described in [QMS015 Quality Improvement]
Continuous improvement is essential for the long term success of the quality system. The effectiveness of procedures within the quality system is ascertained by means of quality system audit and review, internal quality control and external quality assessment. Procedures are also in place to identify and address improvements to the quality system or technical methods and also to identify potential sources on non-conformities.

4.14.8 The laboratory is audited by external organisations in accordance with guidelines .These reviews by external accreditation organisations include accreditation assessments, regulatory agency inspections and health and safety inspections e.g. MHRA,HTA,UKAS and the CQC. The reviews/audits are recorded on Q pulse. Any nonconformities are managed via Q pulse with the appropriate immediate actions and if appropriate corrective/preventative actions taken to ensure continuing compliance with the requirements of this International standard.

4.15 Management review

The management review process is detailed in [PATH032 – Management Review Procedure].
The review is held on an annual basis as a joint pathology exercise (4.15).
The review is available throughout the department via Q-Pulse. An executive summary of the review is sent to UKAS each year as part of a surveillance visit.

5 Technical Requirements

5.1 Personnel

5.1.1 The Human Resources Business Partner team are responsible for the creation, review and monitoring of policies that relate to staff and their working lives. These policies are developed together with the staff side representatives and agreed where appropriate, through the Partnership Forum. The team has a dedicated webpage where all staff can obtain advice and view all current HR policies and procedures.

5.1.2 The Trust has a policy entitled "Safer Employment Policy" which provides advice and information on the employment checks that need to be carried out as part of the recruitment to vacant posts in the Trust. These checks cover staff during pre-employment and whilst in-employment. This includes the procedures to be followed in regard to the following checks:-

- Verification of Identity Checks
- Right to Work Checks
- Registration and Qualifications Checks
- Employment History and References Checks
- Disclosure and Barring Service (formerly CRB) checks
- Occupational Health Checks.

These standards have been developed by NHS Employers and are designed to safeguard patients, staff and the public. The policy has been agreed in consultation with the Trust's Executive Team, Senior Management Team, Workforce Committee and Staff Partnership Forum.

5.1.3 Each post within the laboratory has a job description based on the standard template provided by the Trust. These job descriptions are held by the HR department and copies are stored on Q Pulse for reference.

5.1.4 Each new member of staff attends the standard Trust induction programme as well as having a local induction on their first day in the laboratory. [PATHFORM001 – Local Induction Checklist]

5.1.5 Each department has a dedicated training programme for all grades of staff. These are stored on Q Pulse and reviewed at regular intervals to ensure compliance with local and national guidelines.

5.1.6 Each department has competency assessment documentation for all grades of staff. These are stored on Q Pulse and reviewed at regular intervals to ensure compliance with local and national guidelines. [QMS006 - Competency Assessment] outlines the assessment process, with various training and competency records detailing the requirements to perform assigned tasks.

5.1.7 All medical staff in non-training grades undergo annual appraisal as part of their revalidation cycle according to Trust policy.
Each member of the technical and secretarial staff undergoes annual performance review. This process is guided by Trust wide policies and procedures. Records of annual appraisals are held by the laboratory managers.

5.1.8 The Trust has a policy covering training and development of all staff. Medical and HCPC registered members of staff are expected to maintain their own individual record of CPD in order to comply with regulatory requirements. The department has a regular programme of lunchtime educational meetings for all staff. Laboratory staff are also encouraged to attend other meetings, courses and conferences whether held in-house or offered by external agencies such as professional bodies, manufacturers of equipment or higher educational institutions (HEIs). Limited funding is available for further education of staff from within the department's own budgets and also from CPD monies granted to the Trust by Health Education England (North West). Information pertaining to applications, funding and the roles and responsibilities of staff delivering training can be found in [PATHPOL 005 - Pathology Training Policy]

5.1.9 The laboratory manager is responsible for maintaining the records for each member of staff. Some information is held on file within the laboratory, some within the HR department of the Trust. The Trust holds electronic staff records on the ESR system. The occupational health department maintains records on immunisation and health screening.

5.2 Accommodation and environmental conditions

5.2.1 The Pathology departments are housed in a purpose built unit at the rear of the general wing.

5.2.2 Blood Sciences has separate areas for clinical chemistry, haematology and immunology. The Blood Transfusion laboratory is on the ground floor. The DAWN service is also housed on the ground floor.

Cellular Pathology has separate areas for specimen cut-up, tissue processing/embedding, section cutting/staining, immunohistochemistry/special stains and non-gynaecological cytology preparation. The mortuary is situated close to the Pathology department on the ground floor. There is a dedicated waiting room adjacent to the mortuary for relatives of the deceased.

Consultant and SpR offices are on both the ground and first floor. The departmental secretaries are housed in an office on the ground floor.

The main pathology reception is on the first floor within the blood sciences laboratory. This provides a reception for samples and receiving visitors to the laboratory. Most patient data input is performed in this reception area or the histology cut-up room.

5.2.3 The laboratory has designated storage areas within the confines of the department. There is an external purpose built storage facility for flammable materials located next to the laboratory in the rear courtyard. Some archived Cellular Pathology slides are stored securely underneath the Women and Children's building (on-site). The laboratory also uses Dataspace in Northwich to store archived paraffin blocks and documentation which must be retained for lengthy periods (such as transfusion records).

5.2.4 The Trust provides a restaurant, which is open during normal mealtimes. There are also vending machines for drinks, snacks and confectionery for out of hour's staff. At the main hospital entrance there is a shop selling a range of goods and a café open during hospital visiting hours.
In the Pathology laboratory, off the main laboratory corridor, there is a staff rest room which provides facilities for drinks and storing food. Staff toilets and lockers are found in rooms off the main pathology laboratory corridor.
The pathology seminar room is used for Pathology business and educational meetings. This room may also be used for individual study by trainees and other BMSs.

5.2.5 Phlebotomy for out-patients is performed in a designated room located by the OPD 3 entrance.

5.2.6 The Pathology laboratory's infrastructure is maintained by the Trust's estates department. The IMT department are responsible for the maintenance of the communications and IT network.
The Pathology directorate uses Connected Automated Monitoring/Checkit to monitor the temperature of blood fridges, laboratory fridges and freezers, body stores, incubators and ambient stores. Blood fridges located in Central Labour Suite, Main Theatres, Ellesmere Port Hospital and the Hospice of the Good Shepherd are also monitored by Connected Automated Monitoring/ Checkit.

Entry to the general public is via the main pathology entrance on the first floor, off the main hospital corridor. This allows access to the pre-reception area only for enquiries and sample drop-off. Access to all laboratory areas is barred by secured doors. Staff however, gain access to the laboratory areas by the use of security card or toggle. The security system is administered and maintained by the Facilities department. Cleaning and waste disposal is carried out by staff from the Facilities department.

5.3.1 Laboratory equipment

5.3.1.1 The department has a local policy [PATH024 Equipment, Management and Procurement] and also follows the Trust wide policies on the selection, procurement and purchase of equipment.

The Blood Sciences department has a managed service contract with Beckman Coulter UK which allows for regular upgrade and/or replacement of laboratory analysers and equipment. The Cellular Pathology department is also setting up managed service contracts for some of their items of equipment as they come up for replacement or renewal.

Where equipment is interfaced to the computer system, this has been performed either by or with the agreement of the computer company and the equipment manufacturer/supplier. Full approval for this procedure is obtained from the Trust's IM&T department

5.3.1.2 The laboratory undertakes a period of testing on new equipment before it is placed in general use to ensure results are reproducible and acceptable. This testing forms part of the validation planning process [QMS002 Validation and Calibration].

5.3.1.3 Manufacturers operating and maintenance manuals are held in the Laboratory Manager's office or in the relevant section of the Laboratory.

Where necessary, the manufacturers' manuals are supplemented by documented in-house methods, with information pertaining to the operation, maintenance, and calibration of such equipment.

The purpose of calibration is to ensure optimal measurement of the analyte.

Reference is made to specific equipment guides, methodologies, kit inserts and analyser reference manuals for information on the calibration of methods and equipment for use in the laboratory.

5.3.1.4 All calibrations should be carried out following the recommendations of the manufacturer. Where relevant, equipment is subject to appropriate in-house checks between calibrations to ensure proper functioning. Details of this can be found within in-house documented procedures pertaining to the use of particular items of equipment.

5.3.1.5 Maintenance records for equipment on service contracts are held by the Laboratory / Section Managers and Beckman-Coulter.

Records and certificates pertaining to the calibration of equipment are held by the Laboratory Managers.

The majority of the Blood Sciences laboratory equipment is on service contract with the supplier, Beckman-Coulter, their agent or company contracted to perform such work.

Other equipment e.g. Cellular Pathology equipment, pipettes, printers, scanning system, Air tube system etc. all have service / maintenance contracts. Service contract details are held by the Laboratory Managers on the shared drive.

Equipment not on a service contract is maintained by hospital engineers. Records are kept of all maintenance work performed and any such work performed by BMS staff

Any item of equipment which suffers damage, shows sign of malfunction, or is shown by quality control / calibration or otherwise to be defective and unfit for use, must be immediately withdrawn from service and labelled accordingly. Alternative arrangements shall be made until the item has been repaired and recalibrated as appropriate.

5.3.1.6 The manufacturer or service companies must be informed of equipment failures/malfunctions that have contributed to adverse incidents or accidents. These instances are logged on Q Pulse and the Trust Datix incident reporting system.

The laboratory maintains an equipment inventory in Blood Sciences [DOC158] and Cellular Pathology. These records are also being transferred over to the Q Pulse Assets module.

5.3.1.7 Records from service visits or planned maintenance are held by the Laboratory Managers either in electronic form or on paper and are attached to the relevant equipment entry on Q Pulse.

5.3.2 Reagents and consumables

The Laboratory uses outside services and supplies of adequate quality to sustain confidence in the test results produced.

The procedure [PATH025 Management of Reagents, Calibration and Control Materials] is followed.

Assessment of reagents and suppliers is an ongoing process. Any new reagents are assessed for quality and suitability by relevant staff in the Department before they are put into routine use.

The Trust Procurement Department and Finance Directorate determine the business status of companies and advise if they are thought to be inappropriate. Where no independent assurance of the quality of support services or supplies is available, necessary checks, calibrations or other actions are carried out as appropriate, to ensure that purchased goods comply with specific requirements.

The Blood Sciences Department has a Managed Service Contract with Beckman-Coulter UK Ltd. The Cellular Pathology Department has a Managed Service Contract with GenMed.

An electronic stock management system is in use in Blood Sciences, known as '360 inventory management solutions', which tracks all stock under the managed service contract. This fulfils the requirement for identification of date of receipt, lot numbers, first use and expiry. Stock is scanned in to be received and when placed into use. Auto generated e-mails are sent to the supplier when a low level of stock is triggered, ensuring supplies are always available. It is anticipated that the system will soon be extended to all stock within the Department not currently under contract. The system is detailed in the procedure [DOC31 - Reagent Management].

The Cellular Pathology Department has a paper-based system of stock management. This is detailed in [CPPOL020 Stock control of reagents and laboratory consumables].

5.4 Pre-examination processes

5.4.2 Advice for users

Through consultation and feedback from users (4.1.2.2), the Pathology Directorate has published a Pathology Service Handbook, which is available to its users via the hospital intranet and extranet [QMS008] This contains information on laboratory hours, contact telephone numbers, test repertoire, special collection details etc.

The Anticoagulant Service produces a booklet entitled [ACGUIDE - Guidelines for Anticoagulant Therapy and Coagulation Studies]. Further copies are available on request from the Anticoagulant Service.
The Blood Transfusion Laboratory provides information on the hospital intranet, for example [Transfusion Medicine Handbook, 4th Edition].
Information for patients is also available (E1.3): Chemical Pathology provides information on preparation for tests (E1.4) which require fasting [Fasting Guidelines] and information on Cystic Fibrosis Screening [Sweat Test Information].
Information on point of care testing can be found on the hospital intranet in [POCT – Pathology] and [Blood Glucose Monitoring Policy]
Information on Consent for Post-Mortem Examinations is provided to relatives of the deceased by the Trust's bereavement service.

5.4.3 Request forms

Within the Trust, electronic order entry is used by all wards and the majority of hospital clinics for Blood Sciences requests. An electronic GP ordering system Sunquest ICE is used by the majority of GP Practices. Most Cellular Pathology requests are made on paper but electronic ordering is being made more widely available to Trust users. Both paper and electronic request forms provide relevant boxes/fields for essential information and unique identification of the patient and their correct completion is encouraged (mandatory in the electronic form).
Requesting systems have been developed and modified through liaison with, and suggestions from the service users

5.4.4 Primary sample collection and handling

Advice on the collection of specimens is given in the relevant handbooks.
All packaging and transport boxes conform to current regulations.

An air tube system delivers Blood Sciences samples from certain areas of the hospital directly to the Pathology Sample Reception area or Transfusion Laboratory. Samples from other hospital areas, GP Practices, clinics and community nurses are also received at reception. Specimens for Histology taken in

Theatres and Endoscopy are taken directly to the laboratory cut up room by Portering staff. Reception procedures are described in [PATH2012- Reception: Blood Sciences] and [IMSOP001- Reception of Blood Samples].
Main Pathology Sample Reception is located within the Blood Sciences laboratory on the first floor. Transfusion samples are taken directly into the Blood Transfusion Laboratory on the ground floor.

Samples for tests not available within the Department are sent to referral laboratories, which are, where possible, accredited by UKAS [DOCSOP859- Referral to other laboratories - a general overview] describes the process.

Sample/patient details are recorded on the laboratory computer system, and daily logs are printed, which record the dispatch dates of all samples sent away. Return of reports from referral laboratories is monitored by the BMS staff.

5.5 Examination processes

5.5.1 The laboratory employs examination procedures that have either:
• been validated for use by the manufacturer of analytical instruments or reagent kits
• **Or** are methods that have been published in established textbooks or peer-reviewed texts (journals)
• **Or** are methods that have been recommended by national/international consensus, guidelines or regulations

5.5.1.2 The laboratory verifies methods following [QMS002 Validation and calibration] before implementation into routine use and documents this process on a validation template form [QMSFORM002- Pathology Validation Report Form] For Transfusion related validation [TRANFORM047]

5.5.1.3 The laboratory currently does not use any non-standard methods or laboratory designed/developed methods.

5.5.1.4 The laboratory has a policy for the determination of measured quantity values [QMS009- The measurement of uncertainty in testing].

5.5.2 Biological reference intervals are set by the laboratory based upon national and international guidelines, manufacturer recommendations for instruments in use (verified by the laboratory before use) and also local data based on the testing performed on samples from primary and secondary care in house.
The department managers and clinical leads will perform the review of the Laboratory repertoire of tests annually, including the Biological Reference intervals and clinical decision values [DOC 2048]. These reviews are will be discussed at the Blood Sciences Consultant and Laboratory Meetings, Blood Sciences Management meetings, Immunology Consultant and Laboratory meetings.
New tests and methods are introduced on a planned basis following suggestions from staff, requests by users, recommendations from external bodies or the introduction of new instrumentation. Users are informed of any changes to the reference ranges by communications from the Consultant Head of the Department.

5.5.3 Examination procedures are written as SOPs, which include all the necessary information for completion of the procedure. [QMS017- Writing a standard operating procedure]
A repertoire of laboratory tests can be found in Appendix 3.

5.6 Ensuring the quality of examination results

5.6.1 The laboratory follows defined SOPs for the performance of all tests. There are also defined pre-examination and post-examination processes.

5.6.2 The laboratory has a policy defining quality control procedures [QMS010- QMS Policy for Laboratory Participation in EQA schemes]

5.6.3 The laboratory participates in external quality control schemes appropriate to the repertoire of tests

5.6.4 The laboratory ensures comparability of results by use of daily IQC data and participation in appropriate EQA schemes.

5.7 Post-examination processes

5.7.1 Review of results is carried out by suitably qualified personnel as defined in [QMS011 Review and Reporting of Results]

5.7.2 This standard is fulfilled by procedure [DOC152 - Control of Clinical Material - Pathology], [CPPOL0018 – Slide and Block Retention] and [CPPOL014 – Disposal of refuse, clinical waste and waste chemicals]

5.8 Reporting results

5.8.1 Results that have been transcribed into the system are checked before issue by suitably qualified personnel. If results are delayed e.g. analyser downtime, requesting of further/external testing, the laboratory will inform the requestor.

5.8.2 The laboratory includes comments on the suitability of samples in the report.
Reasons for rejection of samples are given in the report if no procedure is carried out.
The laboratory alerts the user to critical values by the use of flags on Blood Sciences results and interpretative comments where necessary.
The reporting of Cellular Pathology samples follows the guidelines issued by the Royal College of Pathologists. Results are transcribed into the EPR+ system and authorised as described in the Cellular Pathology document [CPMED005 – Consultants Report Entry Screen].

5.8.3 The report format is defined by the laboratory and contains all the elements as required by the standard.

5.9 Release of results

5.9.1 All results for hospital patients can be accessed electronically. The majority of GPs have electronic links by which results for their patients are sent several times each day. Currently paper reports are also sent in addition, but plans are to move to a paperless system for those clinicians for whom it is practicable.
Turnaround times for key tests are monitored through the use of clinical dashboards. These are reviewed monthly by laboratory management as well as the executive team (G1.2).

The laboratory has a policy for issuing reports by telephone or fax which follows the advice given by the IBMS [DOC955 Giving results over the telephone and fax]. There are documented procedures for the telephoning of Blood Sciences results which fall within critical intervals [DOC143 Telephoning Results]. Cellular Pathology follows the RCPath guideline [DOC989-Communication of unexpected results in Cellular Pathology]

5.9.2 Results downloaded from the Blood Sciences analysers are checked against pre-set validation criteria on EPR+. If results are within the criteria set for a particular test, auto-validation occurs. Auto-validation is automatically disabled if internal QC fails. Results which do not meet the auto-validation criteria are authorised, either by state registered BMS or Consultant staff, using critical values and delta checks. Results may be accessed on Remisol or EPR+.

5.9.3 There is a documented procedure for issuing amended reports in Cellular Pathology [CPMED005 – Consultant Report Entry] and Blood Sciences [PATH0250 Amending a report].

5.10 Laboratory information management

5.10.1 The laboratory uses the EPR+ laboratory module which is part of the Trust-wide system.
All users are bound by the Trust' Data Protection Policy (available on SharePoint).

5.10.2 The laboratory has a policy which defines the authorities and responsibilities of all personnel who access the EPR+ computer system. [QMS012- QMS Access to laboratory IT systems].

5.10.3 The Pathology EPR+ Laboratory module incorporates Chemical Pathology, Haematology, Histology, Cytology and Blood Transfusion modules. Day to day maintenance of the hardware and software is managed by the Trust IM&T department. [PATH023 -Management of Data and Information]

The IM&T Directorate has overall responsibility for the Trust's IM&T operations. The directorate comprises of three departments working very closely with one another.

<u>Planning & Development</u>
Systems development and support
Trust-wide clinical systems user training
IM&T projects and programme planning
Web development and document management
Risk management and business continuity planning

<u>Information Services</u>
Information Management
Performance management systems
Clinical reporting
Clinical Coding
Information Governance, Caldicott & Data Protection
Health Records Department

<u>Infrastructure</u>
Infrastructure development and support
Computer and network operations

Telecoms' (including the Switchboard)
Technical Support including the Service Desk
IT security and disaster recovery

Appendix One: Blood Transfusion Quality Manual (to satisfy the requirements of BCSH/MHRA)

This appendix to the Pathology Quality Manual outlines the specifications of the Quality Management System of the Blood Transfusion Laboratory, Countess of Chester Hospital NHS Foundation Trust.

Where the Blood Sciences Department is referred to, it includes the Blood Transfusion Department.
This appendix to the Pathology Quality Manual is set out under recommended headings from the Operational Impact Group, and these are highlighted in blue. Reference to documents used in the Quality Management System [are in brackets].

1 PERSONNEL

1.1 There are competent and appropriately qualified personnel, in sufficient number, to ensure an appropriate service is delivered.

1.2 There is an appropriate organisational structure and approved job descriptions.
The organisational structure of the Blood Sciences Department is documented in Appendix Two of this manual.
The Blood Bank is managed by Mrs Clare Barnard and Mrs Emma Kirkham
The Lead Consultant for Blood Transfusion Is Dr Arvind Pillai MRCPath.

1.3 There is an individual (the Quality Manager) who has designated responsibility and authority to ensure the effective operation of the Quality Management System.

1.4 Staff are provided with timely, relevant and regularly updated training including an induction programme. The Blood Bank Manager ensures all relevant staff receive GMP training and regular updates, every 2 years. These records are retained by the Transfusion Laboratory Managers.

1.5 There are hygiene programmes relating to health and safety; personal hygiene and clothing.
The Health and Safety Policy is set out in [PATH018 Health & Safety Policy] and requires staff to be aware of their responsibilities to Health and Safety. An information leaflet is also available to new starters: [PATHINFO060- Safety Handbook].

The Department Health and Safety Officer is: Martin Langan FIBMS (Pathology Services Manager)

1.6 Regular staff meetings are held to review services. A full list of meetings can be found in the Pathology Quality Manual.

1.7 There is a staff appraisal system. Records are retained by the Departmental Manager or Clinical Director as appropriate.

2 PREMISES AND EQUIPMENT

2.1 Adequate premises and equipment are located and maintained to suit the intended operations. The main Blood Sciences Department is a purpose built unit on the upper floor of the Pathology laboratory. The Blood Transfusion lab is on the ground floor.

Pathology and Laboratory access/security

Entry to the general public is via the main Pathology entrance on the first floor, off the main hospital corridor. This allows access to the pre-reception area only for enquiries and sample drop-off. Access to all laboratory areas is barred by secured doors. Staff gain access to the laboratory areas by the use of security card or toggle. Access to the Blood Transfusion department for laboratory staff is on the ground floor.
The Hospital Security Manager has overall responsibility for maintaining security in Pathology.
Communication systems are available in all areas, and meet the needs of the users.

2.2 There is adequate bench space for work processes, cupboards for storage and a separate ambient temperature storage area. Booking in takes place on a designated bench. Regular cleaning and house-keeping take place to maintain a clean and safe environment.

2.3 There is appropriate office and laboratory space. There is a separate office, adjacent to the Transfusion Laboratory, which is shared by the Senior BMS team and the Transfusion Nurse Practitioners. Separate offices are provided for the consultant medical staff and their secretaries also on the ground floor.

2.4 There are adequate, suitably located staff facilities

The Trust provides a restaurant, which is open during normal mealtimes. There are also vending machines for drinks, snacks and confectionery for out-of-hour's staff. At the main hospital entrance there are shops selling a range of goods.
In the Pathology Laboratory, off the main ground floor laboratory corridor, there is a staff rest room which provides facilities for drinks and storing food. Staff toilets and lockers are found in rooms off the main Pathology Laboratory corridor.

2.5 Where applicable there are adequate facilities for patients. The Blood Sciences Department does not have specific facilities for patients. Haematology and Anticoagulant Clinics are held in the Haematology Oncology Suite, which is on the ground floor adjacent to the laboratory areas. Here patients have a waiting area, and adjoining this, a phlebotomy room and toilet facilities.

2.6 There is appropriate space available for specimen reception, handling, despatch and disposal.
Samples for Blood Transfusion are received through the air tube, either direct from the ward or via first floor reception.

2.7 There are appropriate and adequate data storage, retrieval and communication facilities.
The procedure [PATH023 -Management of Data and Information] is followed to ensure service delivery.
Adequate numbers of PCs are provided.

2.8 The laboratory equipment meets the demands of the service and is properly validated, maintained and calibrated.
The Transfusion Laboratory utilises two Ortho Vision analysers in addition to using manual techniques.

Full commissioning and validation is carried out prior to implementation. SOP [TRDOC035 - Validation Master Plan] sets out the requirements. There are individual SOPs detailing the use, maintenance and calibration of equipment in Transfusion.

2.9 There is adequate and safe provision of lighting, heating, ventilation, power, gases, water and drainage. The main Blood Sciences Department is a purpose built unit on the upper floor of the Pathology laboratory. The Blood Transfusion Unit is on the ground floor.

2.10 There are adequate storage facilities for specimens, reagents and records. Separate storage facilities are provided for documentation and quality records, patient samples, hazardous substances and reagents.
Temperature sensitive storage is kept in monitored areas and units. This includes reagents, specimens and Blood Transfusion products and components.
General consumables are kept in the main hospital stores and requisitioned and distributed when needed. A stock control system is in place. Staff are instructed to ensure only in-date reagents and kits are used and good stock rotation is maintained.

2.11 Blood Bank facilities comply with the current BCSH guidelines and other relevant standards (e.g. BS 4376). Where relevant, they also comply with the requirements of Good Manufacturing Practice as laid out in Eudralex Volume 4 contained in the current version of "Rules and Guidance for Pharmaceutical Manufacturers", the Stationery Office.

2.12 There is a safe working environment in accordance with current legislation. Health and Safety and Risk Assessments are in place to ensure a safe environment for staff and visitors.

2.13 There are appropriately sited facilities available to support training and continuing education. A seminar room is used for Departmental and Pathology wide meetings such as training and management meetings. This room may also be used for individual study by trainees and other BMS staff.

3 DOCUMENTATION

3.1 There is a controlled document system in which written procedures describe the work processes and which are regularly reviewed to keep them error free and up to date. This includes:

a) A summary of the Quality Management System;
This appendix to the Pathology Quality Manual describes the Quality Management System of the Countess of Chester Blood Transfusion Laboratory.
b) Records;
Records are managed and retained in accordance with the Blood Safety and Quality Regulations, 2005.
c) Worksheets;
Paper based worksheets are no longer used in the Transfusion Laboratory. Data transfer is now electronic.
d) Labels;
Labels are utilised throughout the patient testing and issue process. This includes both printed labels and handwritten labels. Their use is described in SOPs [Electronic Issue- TR036], [Group SOPs – TR044, TR046, TR049 AND TR048], [Irradiated Blood and Blood Components – TR053], [LIMS Downtime Procedure – TR057], [Platelets – TR062], [Pre- Analytical Processes in Blood Transfusion – TR072] and [Emergency Blood – TR078].
e) SOPs;

These are managed through the Q-Pulse Document Module.

f) Incident Management System;

The Datix system is used primarily to report all incidents relating to transfusion, the Transfusion Team Leader & Transfusion Nurse Practitioner will report to SABRE when appropriate. [TR071].

g) Change control system;

This is described in SOP [QMS003 - Change Control].

h) Personnel documentation; including organisation chart, job descriptions and training records.

Staff records for each member of staff are kept either in their personal file, by the Departmental Manager, Human Resources department or on the Electronic Record

[QMS006-Competency Assessment] outlines the assessment process, with various training and competency records detailing the requirements to perform assigned tasks. These records are retained by the Senior BMS team.

[QMS001 - Document Control], describes the management of controlled documents issued as either Departmental Standard Operating Procedures or Pathology-wide Procedures.

The Trust has a separate Document Management System known as Share-point, which securely holds all policies and procedures which Trust users require access to. This includes the Pathology Services Handbook. Access to this handbook for GPs is via the Trust internet page.

3.2 Appropriate records are maintained within Health Boards/ Health Authorities/ Trusts. Traceability records for blood and blood components from donor to patient (or final fate if not transfused) need to be available and accessible for 30 years:

The requirement for traceability is set out in an SOP [Traceability SOP – TR096]:

3.3 Compliance with this requirement for traceability will be verified periodically.

Compliance is assessed by the Transfusion Team Leader and Transfusion Nurse Practitioner daily, using reports generated from LIMS.

3.4 Additionally, it is highly desirable that the record keeping dataset be extended to include information about the transfusion.

The Transfusion Nurse Practitioners ensure that the following data sets are maintained for the audit trail:

- The identity of the person who prescribed the blood component - GMC number (or name);
- Details of the 'consent to transfusion';
- The reason for the transfusion;
- The identity of the person who collected the blood (from Blood Bank or Blood Fridge) and the date and time of collection;
- The identity of the person(s) who undertook the pre-transfusion checks;
- The date and time of the transfusion;
- Any adverse events related to the transfusion.

This data capture is achieved using a computerised system and Blood Transfusion therapy chart.

3.5 When electronic, photographic or other data processing systems are used instead of typed/ written documents, the system shall have been validated to demonstrate the data will be appropriately stored and can be accessed throughout the period of storage. Electronic data shall be protected against loss or damage of data during storage.

The IM&T Department follow their validation protocol for storage and retrieval of such data.

4 PROCEDURES

4.1 Procedures will be carried out according to pre-established and documented instructions in accordance with good practice.
Examination procedures are written, which include all the necessary information for completion of the procedure.
Procedures are readily available within the relevant areas / sections of the Laboratory either as hard copy and / or electronically.

4.2 All test methodology should be validated to demonstrate reliable performance before introduction. Tests must be performed by trained staff, using in-date reagents and appropriate controls. Acceptance criteria should be established for all test methods. If acceptance criteria are not met, then test results should not be reported.
Validation takes place prior to introduction of new methodologies and processes.
The methods used in the Blood Transfusion Laboratory and the results obtained are documented: [QMS002-Validation and Calibration] and [TRDOC035- Validation Master Plan].
Before test procedures are changed, users are informed of any changes that may affect results or their interpretation.

4.3 There is a formal, documented system for change control.
This is described in SOP [Change Control – QMS003].

4.4 There is a formal, documented system in which management regularly reviews the performance of the Quality Management System.
There is an annual management review which is undertaken to determine whether the Departments objectives have been successfully completed and provides an opportunity for revising such objectives and plans and the functioning of the quality management system.

4.5 As a minimum, documented procedures should exist for the following key activities:

4.5.1 There is an up to date user manual.
The Pathology Directorate has published a Pathology Service Handbook, which is available to its users via the hospital intranet and internet. This contains information on laboratory hours, contact telephone numbers, test repertoire, special collection details etc.

4.5.2 Request forms for laboratory investigations and specimen labels include provision for unique patient identification and adequate supporting information.
There is a separate dedicated request form for use for Transfusion requests.

4.5.3 Reports of laboratory results are validated prior to despatch, are timely, accurate and comprehensive. They include unique patient identity, date of testing/reporting and name and location of requesting clinician.
Electronic reports are checked by the BMS or Consultant as appropriate. All abnormal results are reviewed prior to reporting and appropriate comments added. All reports are handled and transmitted confidentially. No paper reports are issued for routine testing.

4.5.4 Interpretative reports are unambiguous, comprehensive and clinically relevant.

All interpretative comments are clear and attributable. The authorising person is electronically retained on EPR+.
Comments to clinical end users must take into consideration the amount of clinical information provided.
The laboratory results that are significantly abnormal and require immediate action will be telephoned by a BMS, or Consultant, and an electronic/paper record kept that the result has been telephoned.
Clinical advice is further relayed through various meetings, for example, MDT and GP Network meetings.

4.5.5 There are written procedures relating to specimen collection, handling, retention, despatch and disposal. This includes clear instructions on how to deal with incorrectly labelled specimens and/or improperly completed request documents.
The collection and handling of clinical material is fully documented in the following procedures: [PATH036 – Specimen Collection and Handling]. There is also a guide for phlebotomy [PATHPOL004- Phlebotomy Handbook].
Reception procedures are described in [PATH2012- Reception Blood Sciences], [TR072-Pre-Analytical Processes in Transfusion- Sample Acceptance] and [TR068- Referral of Samples].
There is a separate request form for Blood Transfusion. The samples and forms are labelled with one unique barcode label to identify the request. This is done at Transfusion reception and is described in the procedure [TR072- Pre-Analytical Processes in Transfusion- Sample Acceptance]
Consultant staff monitor requests to ensure they are appropriate and ensure that the methodologies in use are suitable.

4.5.6 If the hospital where the department is sited is a potential receiving centre for a major incident, there is a readily accessible document within the department instructing staff on procedure.
The Blood Transfusion Laboratory follows the procedure set out in [Major Incident Plan – PATH0229], and the Management of a Massive Haemorrhage Policy [DOC3027] and [TR078 - Issue of Un-cross matched Blood / Emergency Blood Issue], [TR0122- Code Red] is available if necessary.

4.5.7 There is a record of all reagents, calibration and quality control material.
The Blood Sciences Laboratory uses outside services and supplies of adequate quality to sustain confidence in the test results produced.
The procedure [PATH025 Management of Reagents, Calibration and Control Materials, TR083 Pre-acceptance testing] is followed.
Assessment of reagents and suppliers is an ongoing process. Any new reagents are assessed for quality and suitability, and their performance validated [TRDOC035 - Blood Transfusion Validation Master Plan] before they are put into routine use.

4.5.8 There is a standard operating procedure for the performance of each test.

4.5.9 There is a standard operating procedure for oral transmission of results.
Telephoning results may be necessary if urgently required or abnormal. The telephone reporting of results is fully documented in the following document: [TR074 -Telephoning Results]

4.5.10 There are standard operating procedures for the regular maintenance of equipment.
The procedure [PATH024 Equipment - Management and Procurement] is followed. There are also procedures for the maintenance of specific items of equipment. Blood Transfusion lab equipment and associated reagents are maintained through a managed service contract with OCD UK. Equipment not managed under this contract is either leased or purchased from other manufacturers to provide a full service.

4.5.11 There is a standard operating policy describing any out of hours service.
This is detailed in [TR025 CPP & role of out of hours worker in transfusion]

4.5.12 In hospitals, a nominated consultant in the microbiology department is responsible for infection control.
Dr Jeremy Gardner is the Consultant Microbiologist with responsibility for infection control.

4.5.13 There are standard operating procedures for the storage, distribution and transport of blood and blood components within and out with the Hospital.
SOPs [TR077- Transport of Blood Components out with the Hospital], [TR076- Transport of Blood Components within the Hospital] describe the procedures, along with SOPs [TR018-Blood Stocks: Receipt and Storage of] and [TR0125 Blood Track Manager and Courier].

4.5.14 There are standard operating procedures for the clinical transfusion process.

Clinical Transfusion Procedures are issued by the Consultant Lead for Blood Transfusion and the Nurse Practitioners. They are available to Trust staff via the Share-point Document Management System.

4.5.15 There are standard operating procedures to ensure the safety of transfusion in all settings.
Minimising risk to staff and patients has been a core consideration when producing all standard operating procedures.

4.5.16 There are standard operating procedures covering temperature controlled storage, its monitoring and management of the "cold chain".
SOPs concerning the cold chain include [TR018-Blood Stocks: Receipt and storage of], PATH028-Temperature Monitoring System], [Transport SOPs TR076 & TR077]

4.5.17 There are standard procedures for the validation and calibration of processes and equipment.
This is detailed in SOP [Validation Master Plan– TRDOC035] and [Validation and Calibration – QMS002]

4.5.18 There are standard operating procedures for the notification of serious adverse events and reactions that satisfy the requirements of the Blood Safety and Quality Regulations 2005.
This is detailed in SOP [SABRE / SHOT Reporting – TR071 Transfusion Incident Reporting].

4.5.19 There are standard operating procedures that allow Blood Banks to accurately, efficiently and verifiably withdraw blood and blood components involved in serious adverse events or reactions or that are judged to have the potential to cause harm to patients.
This procedure is detailed in SOP [Product Recall – TR065].

5 SERIOUS ADVERSE EVENT AND REACTION REPORTING

5.1 Serious adverse events and serious adverse reactions must be notified to the competent authority, or an agency approved by the competent authority, in a timely and efficient manner
The Blood Transfusion incident reporting and procedures have been written in relation to the Blood Safety and Quality Regulations (2005/50). [TR071 – Incident reporting]

5.2 There are procedures that allow Blood Banks to accurately, efficiently and verifiably withdraw blood and blood components involved in serious adverse events or reactions or that are otherwise judged to have the potential to cause harm to patients SOP [Product Recall – TR065]

6 SELF INSPECTION

6.1 There is an ongoing programme of self-inspections (audit) which includes periodic audit of compliance with the "traceability" requirements of the Blood Safety and Quality Regulations 2005.

6.2 There is a programme of external inspection/ accreditation.
The Blood Transfusion Laboratory is accredited by UKAS (ISO15189: 2012), as part of the Blood Sciences Department. The Department is currently fully accredited.

6.3 Blood Banks participate in appropriate external proficiency testing schemes.
The Blood Transfusion laboratory participates in two External Quality Assessment (EQA) schemes (to include BTLP, DAT, TITRE, ERP and FMH). Management of the EQA process is documented in: [TR066- Quality Control - External QC / NEQAS]

6.4 Blood Banks must have a formal policy for internal quality control
The process and use of reference and calibration materials is controlled and set out in [PATH025 – Management of Reagents, Calibration and Control Materials].
Internal Quality Control procedures are set out in [TR064- Quality control - Internal QC].

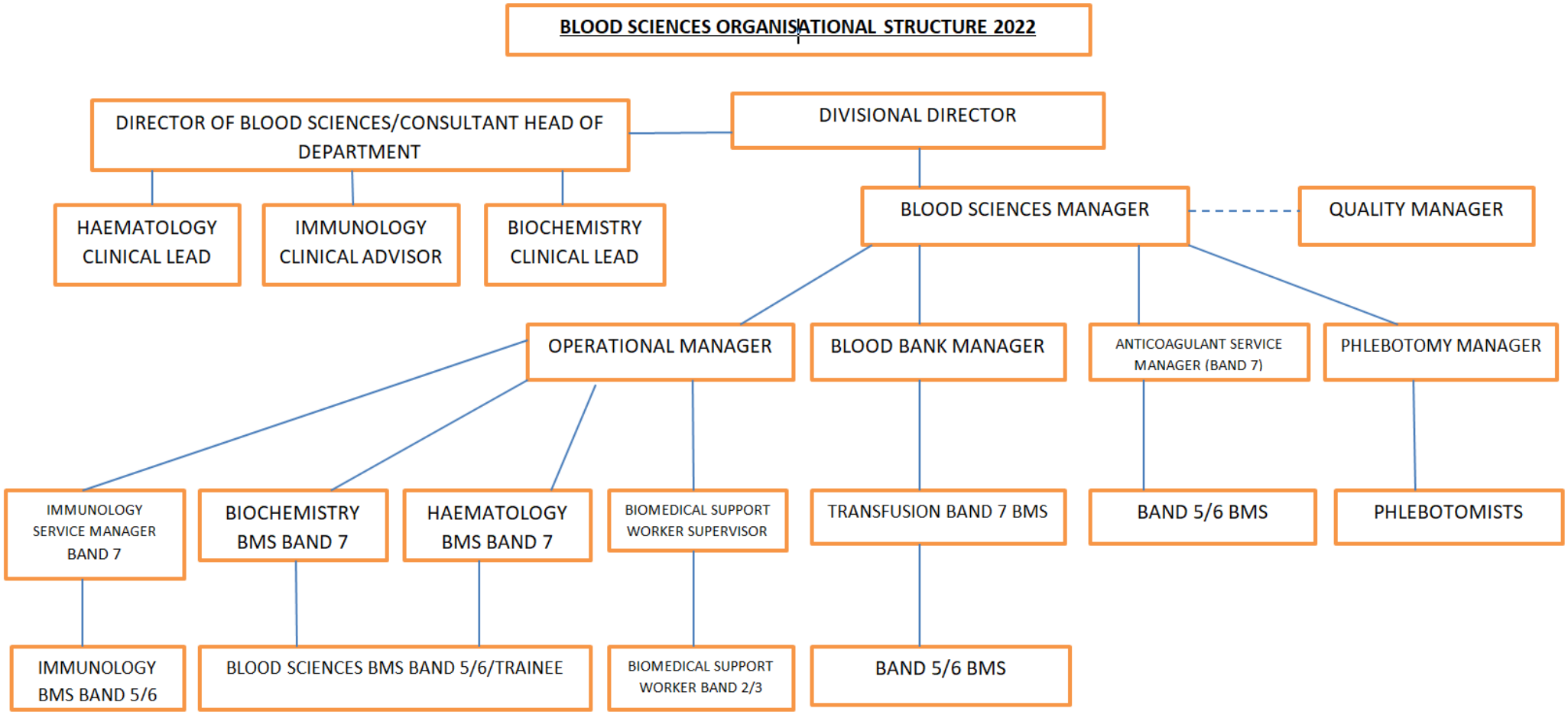
6.5 Where appropriate, the performance in quality assessment schemes is widely publicised in the department with regular formal review.
EQA results are discussed and any issues addressed on a one-to-one basis, as soon as results are returned form the scheme organisers. Findings are displayed in the laboratory and on Q-Pulse & signed by Transfusion Consultant Lead.
There is additionally an annual review meeting to look at EQA findings and trends, which feeds into the Annual Management Review and monthly quality meetings.

6.6 There is a programme of quality assurance evaluation which includes continuing audit of the service provided.
The service provision is regularly reviewed by the Hospital Transfusion Committee and improvements implemented as required.

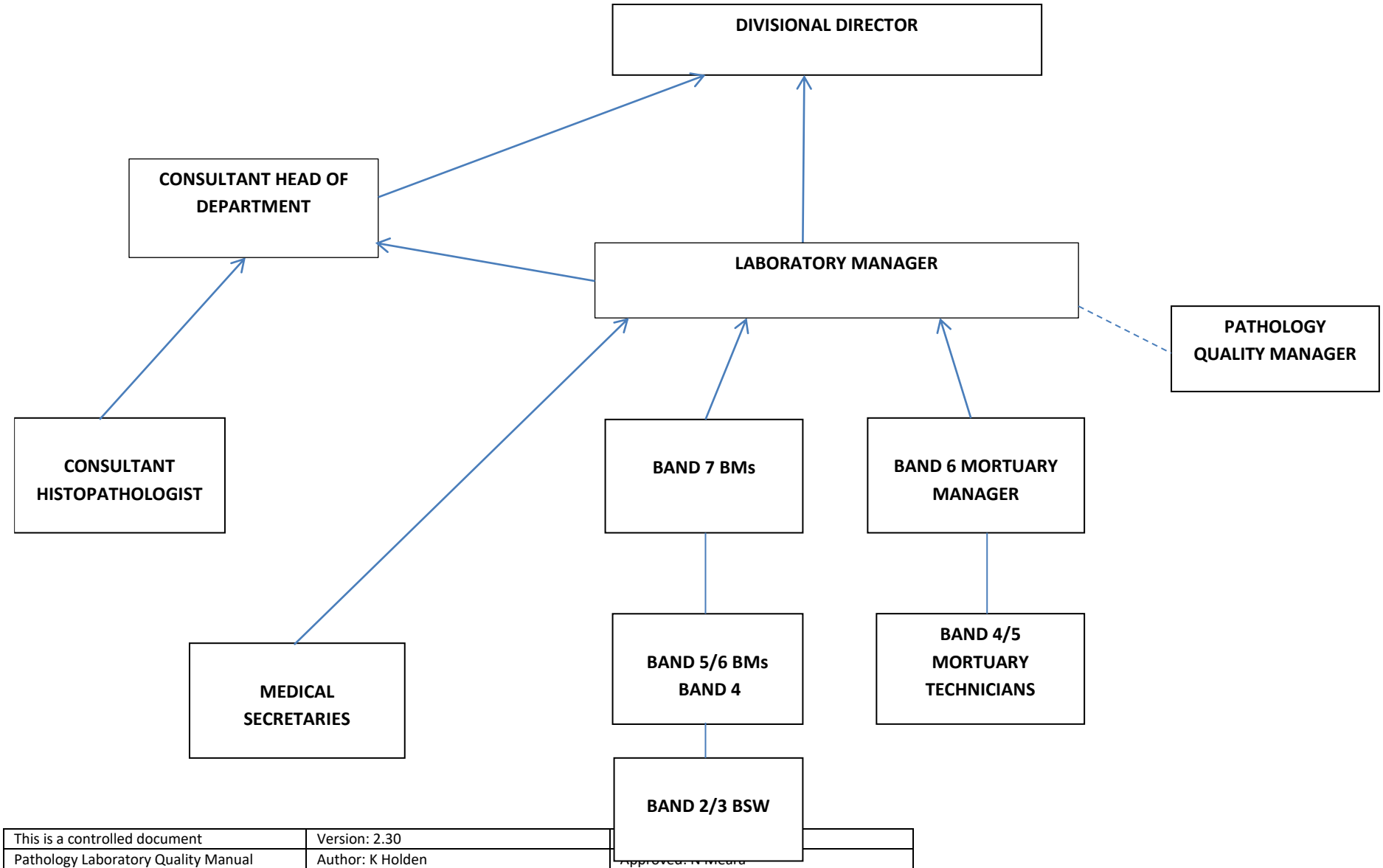
Appendix Two: Departmental organisational charts: see below

Blood Sciences Structure [PATHINFO034]

Cellular Pathology Structure [DOC255]


BLOOD SCIENCES ORGANISATIONAL STRUCTURE 2022
DIRECTOR OF BLOOD SCIENCES/CONSULTANT HEAD OF DEPARTMENT
DIVISIONAL DIRECTOR
HAEMATOLOGY CLINICAL LEAD
IMMUNOLOGY CLINICAL ADVISOR
BIOCHEMISTRY CLINICAL LEAD
BLOOD SCIENCES MANAGER
QUALITY MANAGER
OPERATIONAL MANAGER
BLOOD BANK MANAGER
ANTICOAGULANT SERVICE MANAGER (BAND 7)
PHLEBOTOMY MANAGER
IMMUNOLOGY SERVICE MANAGER BAND 7
BIOCHEMISTRY BMS BAND 7
HAEMATOLOGY BMS BAND 7
BIOMEDICAL SUPPORT WORKER SUPERVISOR
TRANSFUSION BAND 7 BMS
BAND 5/6 BMS
PHLEBOTOMISTS
IMMUNOLOGY BMS BAND 5/6
BLOOD SCIENCES BMS BAND 5/6/TRAINEE
BIOMEDICAL SUPPORT WORKER BAND 2/3
BAND 5/6 BMS

CELLULAR PATHOLOGY STRUCTURE – July 2017



Appendix Three: Repertoire of tests

Our accreditation is limited to those activities described on our UKAS schedule of accreditation found here.

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9061-Medical-Multiple.pdf

Appendix Four: POCT

Point of Care Testing (POCT)

Diagnostic testing has traditionally been performed in the central laboratory in batches, however new smaller robust technology now available has allowed for some testing to be performed at or near the patient.

Point of care testing may be defined as:
All diagnostic testing performed outside the central laboratory by non-laboratory personnel

To achieve the best possible results from POCT devices it is essential that all POCT is implemented in partnership with the Pathology Department and follows the same quality procedures to ensure the results produced are reliable and comparable to those produced by the central laboratory.
Note: POCT is not currently part of the UKAS accreditation held by the Pathology Department.

A POCT Team has been appointed within pathology to oversee this service
A POCT policy is available on the Intranet which acts as a blueprint for all staff considering implementing POCT
The POCT Team will advise on:

- testing methods available
- limitations of testing
- training
- support
- quality assurance
- risk
- Governance
- IT Links

Point of Care Testing within the Trust currently supported by the POCT Team includes:

- Blood Glucose
- Blood Gas
- Cardiac Markers
- Pregnancy Testing- Pre-term labour markers / Placental growth factor (triage meter)
- Urinalysis
- Creatinine Testing
- INR's
- Haemoglobin
- Ketones
- Rotem
- HbA1C

Contact details:

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