Pathology Quality Manual

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Contents

0 Document Definition .................................................................................................................. 5
  0.1 Revision History .................................................................................................................... 5

1 General Information .................................................................................................................. 6

2 Pathology Department .............................................................................................................. 6
  2.1 Blood Sciences ....................................................................................................................... 6
  2.1.1 Haematology ..................................................................................................................... 6
  2.1.2 Blood Transfusion ............................................................................................................. 6
  2.1.3 Chemical Pathology .......................................................................................................... 6
  2.1.4 Point of Care Testing ........................................................................................................ 6
  2.1.5 Specimen Reception .......................................................................................................... 7
  2.2 Microbiology ........................................................................................................................ 7
  2.3 Cellular Pathology incorporating Mortuary and Bereavement Services ................................ 7
  2.3.1 Cellular Pathology ............................................................................................................ 7
  2.3.2 Mortuary .......................................................................................................................... 7

3 Scope of The Quality Manual .................................................................................................... 8

4 Quality Policy (4.1.2.3) [PAT-P-012] ....................................................................................... 9

5 Organisation, Responsibilities and Authorities .......................................................................... 10
  5.1 Relationship to the Host Organisation ................................................................................... 10
  5.2 Clinical Divisions Structure ................................................................................................. 11
  5.3 Divisional Structure ............................................................................................................. 12
  5.4 Pathology Services Structure ............................................................................................... 13
  5.5 Organisation and Management ........................................................................................... 14
    5.5.1 Associate Medical Director ............................................................................................ 14
    5.5.2 Divisional Director ......................................................................................................... 14
    5.5.3 Head of Pathology and Imaging ..................................................................................... 14
    5.5.4 Pathology Clinical Lead/s ............................................................................................. 15
    5.5.5 Consultant Leads ............................................................................................................ 15
  5.6 Laboratory Managers ............................................................................................................ 16
  5.7 Pathology Quality and Customer Engagement Manager (4.1.2.7) ..................................... 16
  5.8 Pathology Information Technology Applications Specialist ............................................. 16

6 Pathology Meetings (4.1.2.6 & 4.13t) ..................................................................................... 17
  6.1 Pathology Management Committee ..................................................................................... 17
  6.2 Pathology Health and Safety Meetings (H&S) (5.2.1 & 5.2.2) ............................................. 18
  6.3 Pathology Training Meeting (5.1.5, 5.1.6 & 5.1.7) ............................................................ 18
  6.4 Pathology IT Meeting (5.10.3) ............................................................................................ 19
  6.5 Pathology Quality Working Group (4.1.2.4 & 4.2) ............................................................. 19
  6.6 Department Management Meetings ..................................................................................... 20
  6.7 Departmental Staff Meetings ............................................................................................... 20
7  Management requirements .............................................................................................................. 22

7.1 Organisation and Management (4) .............................................................................................. 22
7.2 Needs and Requirements of Users (4.1.2.2) .............................................................................. 22
7.3 Ethical Conduct (4.1.1.3) ............................................................................................................. 22
7.4 Quality Policy (4.1.2.3) .............................................................................................................. 23
7.5 Quality Management System (4.2) ............................................................................................. 23
7.6 Quality Objectives and Plans (4.1.2.4) ..................................................................................... 23
7.7 Quality Manual (4.2.2.2) ............................................................................................................ 23
7.8 Quality Manager (4.1.2.7) ......................................................................................................... 23
7.9 Document Control (4.3) ............................................................................................................ 23
7.10 External Services and Supplies (4.6) ....................................................................................... 23
7.11 Control of Process and Quality Records (4.13) ...................................................................... 24
7.12 Control of Clinical Material (5.4.6, 5.4.7, 5.7.2 & 5.7.3) ........................................................... 24
7.13 Management Review (4.12 & 4.15) ......................................................................................... 24

8  Personnel ...................................................................................................................................... 25

8.1 Staffing (5.1) ............................................................................................................................. 25
8.2 Personnel Management (5.1.1) ................................................................................................. 25
8.2.1 Staff Orientation and Induction (5.1.4) ................................................................................. 26
8.2.2 Job Description and Contracts (5.1.3) .................................................................................. 26
8.2.3 Personal Appraisal Development Review (5.1.7) ................................................................. 26
8.2.4 Personal Files and Staff Records (5.1.9) ............................................................................... 26
8.2.5 Staff Meetings and Communication (4.1.2.6) ..................................................................... 27
8.2.6 Staff Training and Education (5.1.5 & 5.1.8) ......................................................................... 27

9  Accommodation and environmental conditions (5.2) ............................................................... 29

9.1 Health and Safety (5.2.1) .......................................................................................................... 29
9.2 Staff Responsibilities for Health and Safety (5.1.5d) ................................................................. 29
9.3 Occupational Health .................................................................................................................. 30

10 Laboratory equipment, reagents and consumables (5.3) ............................................................ 31

10.1 Management of Equipment (5.3.1) ......................................................................................... 31
10.2 Management of Laboratory Reagents and Consumables (5.3.2) ........................................... 32

11 Management of data and information (5.10) ................................................................................ 33

12 Pre-Examination Processes (5.4) ............................................................................................... 34

12.1 Information for Users and Patients (5.4.2) .............................................................................. 34
12.2 Request Form (5.4.3) .............................................................................................................. 34
12.3 Specimen Collection and Handling (5.4.4) ............................................................................. 34
12.4 Specimen Transportation (5.4.5) ............................................................................................ 35
12.5 Specimen Reception (5.4.6) .................................................................................................... 35
12.6 Urgent Samples (5.4.6f) .......................................................................................................... 35
12.7 Referrals to Other Laboratories (4.5) ..................................................................................... 36

13 Examination Processes (5.5) ......................................................................................................... 37
13.1 Selection, Verification and Validation of Examination Procedures (5.5.1) ........................................... 37
13.2 Documentation of Examination Procedures (5.5.3) ................................................................. 37
13.3 Interlaboratory Comparisons (5.6.3) ......................................................................................... 37

14 Post Examination Processes (5.7) ........................................................................................................ 38
14.1 Review of Results (5.7.1) .............................................................................................................. 38
14.2 Storage, Retention and Disposal of Clinical Samples ................................................................. 38

15 Reporting and release of results (4.7, 5.8, 5.9) ............................................................................. 39
15.1 Clinical Advice and Interpretation (4.7) ...................................................................................... 39

16 Evaluation and audits, including the identification and control of nonconformities (4.8, 4.9 & 4.14) ......................................................................................................................... 40
16.1 Assessment of User Feedback and Complaints (4.8, 4.14.3) ...................................................... 40
16.2 Staff Suggestions (4.14.4) ............................................................................................................ 40
16.3 Internal Audit of Quality Management Systems (4.14.5) ......................................................... 40
16.4 Risk Management (4.14.6) ............................................................................................................ 41
16.5 Quality Indicators (4.14.7) .......................................................................................................... 41
16.6 Reviews by External Organisations (4.14.8) ............................................................................. 41
16.7 Identification and Control of Nonconformities (4.9) .............................................................. 42

17 Appendix A ......................................................................................................................................... 43
0 DOCUMENT DEFINITION

0.1 Revision History

Detailed in Q-pulse document control revision history.
1 GENERAL INFORMATION

Great Western Hospitals NHS Foundation Trust (the organisation) is the sole legal entity for the Pathology service and is held legally responsible for its activities (4.1.1.2).

2 PATHOLOGY DEPARTMENT

The Pathology Department falls within the Division of Diagnostics and Outpatients.

There are three laboratories within the Pathology service providing routine and emergency services across the organisation as detailed below.

The Pathology laboratories do not provide any Tertiary services.

2.1 Blood Sciences

2.1.1 Haematology

Haematology is concerned with the analysis of blood cells and blood-clotting parameters, using automated instruments to aid the diagnosis and treatment of diseases such as anaemia, leukaemia and deep vein thrombosis (DVT). They also use special techniques to analyse blood cells by microscopy to help to diagnose illness or the progression of treatment.

2.1.2 Blood Transfusion

Blood Transfusion provides blood and blood products to patients with acute blood loss, anaemia, clotting problems and also supports leukaemia cases during chemo- and radiotherapy. Biomedical scientists in the blood transfusion laboratory are concerned with the identification of individuals’ blood groups and finding donated blood products that best suit the patient.

2.1.3 Chemical Pathology

Chemical Pathology is the study of chemical and biochemical mechanisms of the body in relation to disease. A chemical pathology department within pathology provides a link between medicine and the basic sciences employing analytical and interpretative skills to aid the clinician in the prevention, diagnosis and treatment of disease.

2.1.4 Point of Care Testing

Blood Sciences provides the supervision and management of Point of Care Testing (POCT) with the Trust and community via the Point of Care Testing Coordinator and committee. POCT or near-patient testing is testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient.
2.1.5 Specimen Reception

The specimen reception area receives and sorts specimens from both inside and outside the hospital including GPs. They input Pathology requests into the laboratory information system (LIMS) and prepare and distribute specimens to appropriate departments.

2.2 Microbiology

The Microbiology laboratory provides a routine specialist and emergency analytical and interpretive service for hospital and GP surgeries within the Wiltshire and Swindon areas. The laboratory routinely process patients’ samples including swabs, urine, blood and other body fluids, and serology, both routine for Ante-natal, Occupational Health and Genito-Urinary Medicine Clinics and specialist diagnostic serology. Specialist and Reference test services are used where necessary. The total number of laboratory samples processed is in excess of 270,000 samples per annum. Medical Microbiologists lead the service and give advice on the investigation and management of infectious diseases, antibiotic usage and surveillance of disease in the hospital and in the community. Clinical and infection control advice is given at the bedside during ward/department visits or via the telephone.

2.3 Cellular Pathology incorporating Mortuary and Bereavement Services

2.3.1 Cellular Pathology

The Cellular Pathology department receives tissue or fluid specimens from patients, taken at surgical operations, clinics, or post-mortem examination. Diseases such as cancer are diagnosed by looking for abnormal features in cells. Examinations of the cells, tissues and organs are made to determine diagnosis and information on further treatment. The specimens are processed and stained for microscopic examination to determine the underlying disease process.

The department also offers fertility and post-vasectomy semen analysis.

2.3.2 Mortuary

The Hospital also houses the mortuary and post-mortem room.

The mortuary is licensed by the Human Tissue Authority to provide storage of the deceased and post mortem examination for both the community and the hospital. Services are provided to the Coroner and include close working with funeral directors, laboratories, police and hospital staff.
3 SCOPE OF THE QUALITY MANUAL

This Quality Manual describes the Quality Management System of the Pathology Department. Throughout the text there are references to BS ISO 15189:2012 Standards (in brackets) and to procedures/policies [indicated by square brackets], written in fulfilment of these standards.

This Quality Manual (4.2.2.2) fulfils two functions. It describes the scope of the Quality Management System for the benefit of the laboratory’s own management and staff, and it provides information for users and for inspection/accreditation bodies.

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

The sections of the standards relate to each other in the following manner. Section 1 describes the organisation of a laboratory and its quality management system, which uses resources (Sections 2, 3 and 4) to undertake pre-examination, examination and post-examination processes (Sections 5, 6 and 7). The Quality Management System and the examination processes are continually evaluated and quality assured (Section 8). The results feed back to maintain/improve the quality management process where required and to ensure that the needs and requirements of users are met.

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<thead>
<tr>
<th>Section in the Quality Manual</th>
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<tbody>
<tr>
<td>Section 1</td>
<td>Organisation and management responsibility (4.1, 4.2 &amp; 4.3)</td>
</tr>
<tr>
<td>Section 2</td>
<td>Personnel (5.1)</td>
</tr>
<tr>
<td>Section 3</td>
<td>Accommodation and environmental conditions (5.2)</td>
</tr>
<tr>
<td>Section 4</td>
<td>Laboratory equipment, reagents and consumables (5.3 &amp; 5.9)</td>
</tr>
<tr>
<td>Section 5</td>
<td>Pre-examination processes (5.4)</td>
</tr>
<tr>
<td>Section 6</td>
<td>Examination processes (5.5 &amp; 5.6)</td>
</tr>
<tr>
<td>Section 7</td>
<td>Post-examination processes (5.7 &amp; 5.8)</td>
</tr>
<tr>
<td>Section 8</td>
<td>Identification and control of nonconformities (4.9)</td>
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4 QUALITY POLICY (4.1.2.3) [PAT-P-012]

The Pathology Department provides Microbiology, Cellular Pathology, Blood Sciences, Blood Transfusion, Point of Care Testing and Mortuary services to the Great Western Hospitals NHS Foundation Trust, Swindon Clinical Commissioning Group (CCG), Wiltshire CCG and other users where such arrangements have been made.

The management of the Pathology Department is committed to delivering a service that is compliant with the requirements for Medical Laboratories set by the International Standard Organisation (ISO 15189:2012), Health and Safety Executive (HSE), Medicines and Healthcare Products Regulatory Agency (MHRA), Human Tissue Authority (HTA) and Clinical Pathology Accreditation (UK) Ltd (CPA).

The Pathology management team is fully committed to the ongoing improvement of laboratory services through the continual assessment of the Pathology Quality Management System and the establishment and annual review of quality objectives.

The management of the Pathology Department is committed to good professional practice and the provision of examinations that are fit for intended use to ensure the delivery of a high quality service that meets the requirements of its users. This commitment is reflected in the core values of the Quality Management System:

- The development of a friendly working environment which supports training and encourages the retention and recruitment of committed, highly professional staff.
- A commitment to maintaining a laboratory environment, in compliance with relevant legislation, to ensure the health, safety and welfare of staff and visitors.
- The provision of information on the collection, transportation and handling of all specimens to ensure the validity of results of laboratory examinations.
- The review of test repertoire, in conjunction with users, to ensure it is fit for intended use.
- The procurement and maintenance of appropriate equipment, reagents and consumables to enable the provision of quality examinations of specimens.
- The reporting of high quality examination results in a timely, confidential, accurate and clinically useful manner.
- The provision of advice, in the context of clinical information, to support patient management.
- The engagement with users to ensure that the Pathology service continues to meet their needs and requirements.

Dr Alex Sternberg  
Pathology Clinical Lead

Robin Jones  
Deputy Divisional Director, Diagnostics and Outpatients

11/05/2016
5 ORGANISATION, RESPONSIBILITIES AND AUTHORITIES

5.1 Relationship to the Host Organisation

The Pathology departments fall within the Division of Diagnostics and Outpatients of the Great Western Hospital NHS Foundation Trust.

The Pathology departments are also associated with the following external organisations:

- United Kingdom Accreditation Service (UKAS)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Human Tissue Authority (HTA)
- NHS Blood and Transplant (NHS BT)
- HM Coroner (HMC)
- Thames Valley Cancer Network
- National Antenatal Screening Programme
- National Bowel Cancer Screening Programme (BCSP)
- Swindon Chlamydia Screening Programme
- Public Health England (PHE)
- Royal College of Pathologists (RCPPath)
- Institute of Biomedical Sciences (IBMS)
- Health and Care Professions Council (HCPC)
- United Kingdom National External Quality Assessment Service (UK NEQAS)
- LabQuality External Quality Assurance
5.2 Clinical Divisions Structure

Nerissa Vaughan  
Chief Executive

Adrian Griffiths  
Interim Chief Operating Officer

Douglas Blair  
Director of Community

Services

Women’s & Children’s  
Dr Janette Armstrong  
Associate Medical Director

Diagnostics & Outpatients  
Dr Helen Jones  
Associate Medical Director

Planned Care  
Mr Adam Brooks  
Associate Medical Director

Unscheduled Care  
Dr Elizabeth Price  
Associate Medical Director

Deputy Divisional  
Modern Matrons

Community Midwifery, Swindon, Wilts

Speech and Language Child and Children’s Bereavement Counselling

Children’s Outreach Nursing Team

Safeguarding Vulnerable Children

Children’s Services (PCT and SBC)

White Horse Birth Centre

Director

Child Protection (Trustwide)

Associate Medical Director

Teresa Harding  
Divisional Director

Christina Rattigan  
Head of Midwifery

Sarah Merritt  
Divisional Director of Nursing

Paed/Gynaec

Deputy Divisional  
Modern Matrons

Division (plus Wiltshire wide) Includes:

- Child Protection (Trustwide)
- Children’s Bereavement Counselling
- Children’s Outreach Nursing Team
- Children’s LD Service
- Children’s Medical Services
- Community Midwifery, Swindon, Wilts
- Community Child Health
- Complex care
- Early Pregnancy Unit
- Gynaecology
- Health Visiting - Wiltshire
- Maternity
- Obstetrics
- Paediatrics (Acute / Community)
- SCBU
- Safeguarding Vulnerable Children (South/Wiltshire)
- School Health Service - Wiltts
- School Nursing - Wiltts
- Speech and Language Child and Adult

Wards/Units:

- Beech Ward
- Children’s Unit
- Delivery Suite
- Hazel Ward
- SCBU
- White Horse Birth Centre - GWH

Prime Link to:

Swindon and Wiltts

Children’s Services (PCT and SBC) Education

Division Includes:

- Anticoagulation
- Breast Screening
- Cancer Services and Research
- Gynaecology
- Chaplaincy
- Clinical Haematology
- Dermatology
- Diabetes (Acute)
- GUM (Sexual Health)
- Health Records
- Medical Photography
- Mortuary & Bereavement
- Nutrition & Dietetics (Acute)
- Outpatient Booking Centre
- Outpatients Departments
- Palliative Care / End of Life
- Pathology Services
- Pharmacy
- Phlebotomy
- Radiology Imaging
- Rheumatology
- Therapies (Acute)
- Trust Equipment
- VTE

Wards/Units:

- Coate Water
- Day Therapy Unit
- Dove
- Disprey
- Wren

Prime Link to:

Strategic Clinical Cancer Network

Prospect Hospice

Onsite Renal Unit

Division Includes:

- Anaesthetics
- Audiology
- Critical Care Outreach
- Day Surgery
- Decontamination (Community)
- Dentistry (Community)
- Ear Nose & Throat
- Elective Admission (incl. Pre Operative Assessment)
- Falls Team
- Flexible Cytoscopy
- Fracture Clinic
- General Surgery
- HSU
- ITU & HDU
- Ophthalmology
- Oral Surgery
- Orthodontics (Adults)
- Orthopaedics
- Orthotics & Maxillo Facial Surgery
- Pain Management
- PICC line service
- Plastic Surgery
- Private Patient Services
- Stoma Nursing
- Theatres
- Trauma & Orthopaedics
- Urology
- Vascular Nurse Specialists

Wards/Units:

- Aldbourne
- Ampney
- Cherwell
- GTU/HDU
- Melksham
- Shalbourne Clinic
- Shalbourne Suite
- Surgical Assessment Unit
- Trauma Unit

Prime Link to:

Ambulance Service and Transport

Community Rehabilitation Team

Emergency Planning (Trustwide)

Mental Capacity (Trustwide)

Occupational Therapy

Out of Hours Service

Savernake

Social Services

Speech & Language Therapy

SWCC

Tertiary CHD Network

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5.3 Divisional Structure

**CLINICAL LEADS**
- **Pathology**
  - Dr Alex Stormberg: 0303 P2622
  - Dr Melanie Wilson: 4801
- **Radiology**
  - Dr Yvonne Taylor: 4277
- **Breast Screening**
  - Dr Nick Ridley: 5069 P2010
- **Outpatient Medical Specialties**
  - Dr Brian Blankenhorn: 4299
- **Cancer Services including Dermatology & Haematology**
  - Dr Lindsay Whitcham: 4370
- **Mortuary**
  - Dr Lawrence John: 4252

**DIAGNOSTICS & OUTPATIENTS DIVISION**

**Associate Medical Director**
- Helen Jones: 5203 P2622
  - PA: Rebecca Maul: 4652

**Deputy Divisional Director**
- Robin Jones: 5062
  - PA: Rebecca Maul: 4652

**Divisional Director**
- Judith Ratcliffe: 4678
  - PA: Rebecca Maul: 4652

**Interim Divisional Director of Nursing, Quality & Patient Experience**
- Carolanne Whitham: 4993 P1225

**Chaplaincy Team Manager**
- Steve Henderson: 4288 P2506

**Director of Pharmacy and Medicines Optimisation**
- Susan Mankelow: 5034
  - PA: Barbara Cox: 2035

**Clinical Business Manager (Therapies & Outpatient Medical Specialties)**
- Mark Goodwin: 4644

**Head of Outpatient Medical Specialties Services**
- (Diabetes & Rheumatology)
  - Kath Brown: 4447

**Physio - GWH (Acute)**
- Sharon Jameson: 5126 P2116

**Physio - GWH (IT & O)**
- Louise Holmes: 5119

**Physio - GWH (Outpatients)**
- Karen Hawkins: 5092

**Dietetics - Swindon**
- Linda Webb: 5147

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As at 6th June 2016

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5.4 Pathology Services Structure

**Additional Pathology Support**
- Pathology Clinical Applications Specialist (x1)
- Information Governance Facilitator (x1)

**Department of Pathology**

**Date of Issue:** 4th October, 2016

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5.5 **Organisation and Management**

The organisational relationships of the Pathology Services within the Division of Diagnostics and Outpatients of the Trust are shown in Section 5.2, 5.3 and 5.4.

5.5.1 **Associate Medical Director**

The Associate Medical Director is responsible to the Medical Director of the Hospital Trust. The post holder is responsible for the clinical and administrative functions of the directorate and heads the directorate.

Pathology is represented at Trust Management Board meetings by the Divisional Associate Medical Director and feedback is provided to scheduled Pathology Management Committee Meetings.

5.5.2 **Divisional Director**

The operational and administrative activities of the Diagnostics and Outpatient Services are devolved to a Divisional Director.

The Divisional Director has organisation wide responsibility for the operational management and modernisation of Pathology services within the organisation. The Divisional Director works with the Deputy Divisional Director, Associate Medical Director, Head of Pathology and Imaging and Discipline Team leads to develop and implement the planning and performance management agenda for Pathology across the organisation. The Divisional Director provides operational management leadership to the Pathology departments including working with the Pathology department management teams to ensure effective budget management and monitoring, workforce management and planning and ensuring effective use of resources and equipment. The Divisional Director plays a lead role in modernisation of the service in line with local and National strategies.

5.5.3 **Head of Pathology and Imaging**

The Head of Pathology and Imaging has specific responsibility for management of Pathology Services and in the context of BS ISO 15189:2012 performs the Laboratory Director role (4.1.1.4) for the Pathology Services. The Head of Pathology and Imaging is accountable to the Divisional Director who is responsible for directing the overall quality and financial performance of the Division.

Duties and responsibilities of the Laboratory Director, including those duties delegated to others, are listed below:

- Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.

- Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required.

- Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of users. Recruitment, training and competency duties are delegated to Laboratory Managers.
• Ensure the implementation of the quality policy. Delegated to the Pathology Quality and Customer Engagement Manager.

• Implement a safe laboratory environment in compliance with good practice and applicable requirements, delegated to Laboratory Managers.

• Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate. This duty is delegated to the Pathology Clinical Lead/s.

• Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results. This duty is delegated to the Pathology Clinical Lead/s.

• Select and monitor laboratory suppliers, delegated to Laboratory Managers.

• Select referral laboratories and monitor the quality of their service (4.5). This duty is delegated to the Laboratory Managers.

• Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations.

• Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services. Performance standards are monitored within the context of the individual Pathology disciplines (delegated duty of Laboratory Managers), Pathology Management Committee meetings, Divisional Board meetings and Trust Performance meetings.

• Monitor all work performed in the laboratory to determine that clinically relevant information is being generated. This duty is delegated to the Laboratory Managers and Pathology Clinical Lead/s.

• Address any complaint, request or suggestion from staff and/or users of laboratory services (4.8, 4.14.3 & 4.14.4).

• Design and implement a contingency plan to ensure that essential services during emergency situations or other conditions when laboratory services are limited or unavailable. This duty is delegated to the Laboratory Managers.

• Plan and direct research and development, where appropriate. This duty is carried out in partnership with the Laboratory Managers and/or Pathology Clinical Lead/s.

5.5.4 Pathology Clinical Lead/s

The Pathology Clinical Lead/s are accountable to the Divisional Associate Medical Director who is responsible for directing the overall clinical performance of the Division.

5.5.5 Consultant Leads

Consultant Leads are responsible for the professional direction of laboratory functions of their specialties. Laboratory/Department managers are assigned to each of the departments. Clinically,
The Laboratory Managers are responsible to the relevant Lead Consultant of each discipline who, in turn, are responsible to the Pathology Clinical Lead and subsequently, Associate Medical Director.

5.6 **Laboratory Managers**

The Pathology laboratory managers are accountable to the Pathology Clinical Lead/s for clinical matters and to the Head of Pathology and Imaging for nonclinical matters.

The Pathology laboratory managers are accountable for the day-to-day operational management of the Pathology Departments, being responsible for managing, motivating and effectively leading the technical and support staff in the delivery and development of high quality Laboratory services. Pathology laboratory managers are responsible for quality management within the department and participation in quality management across the departments of Pathology. The Pathology laboratory managers are accountable for the financial performance of Pathology departments and monitoring the delegated management of individual departmental budgets where appropriate.

5.7 **Pathology Quality and Customer Engagement Manager (4.1.2.7)**

The Pathology Quality and Customer Engagement Manager ensures, on behalf of laboratory management, that the Pathology Departments Quality Management System (QMS) functions correctly. The Pathology Quality and Customer Engagement Manager has a defined role for ensuring a Quality Management System is implemented and maintained and reporting to laboratory management on the functioning and effectiveness of the quality management system and any need for improvement.

The Pathology Quality and Customer Engagement Manager leads on customer engagement across Pathology, liaising with service users including GWH clinicians, GPs, CCG leads and patients to ensure delivery of a service which meets, and responds to changes in, the needs and expectations of service users, and ensures the promotion of awareness of users’ needs and requirements throughout Pathology.

5.8 **Pathology Information Technology Applications Specialist**

The Pathology Information Technology (IT) Applications Specialist is a joint appointment between the Information Technology Department and Pathology Departments. The Pathology IT Applications Specialist is the systems manager of the Laboratory Information System (LIMS).

The Pathology IT Applications Specialist supports the management, maintenance and development of IT services in the Pathology Departments, encompassing the introduction of the new technologies and initiatives within the Pathology Department whilst supporting the overall organisation IT strategy.
6 PATHOLOGY MEETINGS (4.1.2.6 & 4.13t)

6.1 Pathology Management Committee

The Pathology Directorate meetings are scheduled to meet a minimum of ten times per year.

Function

The Pathology Management Committee is an operational committee monitoring service provision, implementation and progress of plans, including any impediments and resource challenges. The committee reports to the Pathology Management Review Committee.

The Committee:

- Monitors progress of ongoing actions from previous meetings as listed in the action tracker.
- Review Directorate and Trust senior meeting feedback.
- Reviews financial position of the Pathology disciplines, the Directorate and the Trust.
- Reviews HR position of the Pathology disciplines and the Directorate. This encompasses workforce capacity and vacancies (including turnover and temporary staffing), management of attendance and sickness absence, mandatory training compliance and performance review (appraisals).
- Reviews outliers of the IT Report produced for scheduled Pathology IT meetings.
- Review Health and Safety output and actions from scheduled Pathology Health & Safety meetings and Trust Health & Safety Committee meetings.
- Reviews Clinical Governance pertaining to the Pathology disciplines. This encompasses IR1/NCN review, Risk register review, Quality outliers, Complaints/compliments, MHRA/CPA/HTA and ISO15189.
- Review progress against Quality Objectives agreed at Pathology Annual Management Review meeting.
- Discuss any other departmental operational issues or process improvements, including equipment.

Membership

Diagnostics & Outpatients Deputy Divisional Director
Head of Pathology & Imaging
Pathology Departmental Managers (and/or nominated deputies)
Mortuary Manager
Pathology Clinical Lead Consultant(s)
Departmental Clinical Lead Consultant(s)
Pathology Quality and Customer Engagement Manager

Representation may be invited from:
Pathology Clinical Applications Specialist
Diagnostics & Outpatients Finance Business Partner
Diagnostics & Outpatients HR Business Partner
6.2 Pathology Health and Safety Meetings (H&S) (5.2.1 & 5.2.2)

The Pathology Health and Safety meetings are scheduled to meet monthly.

Function

The Pathology Health and Safety Committee addresses issues that affect any aspect of the Pathology Service. The committee reports to the Pathology Management Committee and Trust Health and Safety Working Groups.

The Committee:

- Assists in the formulation, dissemination and review of policies, procedures and programs relating to health and safety in Pathology,
- Monitors workplace hazards and the effectiveness and appropriateness of measures taken to protect health and safety,
- Reviews reports on health and safety matters, such as reports on hazards, accidents, injuries, near misses, and environmental or medical monitoring,
- Considers health and safety matters referred to it by the departmental Health & Safety Representatives and the Trust health and safety committee,
- Facilitates co-operation between management and employees and provides a forum for participation by employees in developing and implementing measures designed to ensure the health and safety of the Laboratory Community,
- Makes recommendations aimed at improving health and safety and assists in implementing these recommendations and monitoring their effectiveness and
- Adopts such measures as the Committee determines.

Membership

Head of Pathology & Imaging
Laboratory Manager Representative
Pathology Quality and Customer Engagement Manager
Microbiology Staff Representative
Cellular Pathology Staff Representative
Blood Sciences Staff Representative
Mortuary Staff Representative
Phlebotomy Staff Representative
Specimen Reception Staff Representative

6.3 Pathology Training Meeting (5.1.5, 5.1.6 & 5.1.7)

The Pathology Training meetings are scheduled to meet four times a year.

Function

The Pathology Training Forum is a consultative committee that discusses Training requirements, Training plans and other issues relating to Training across Pathology.
The Forum:

- Discusses and reviews training needs across Pathology, both departmental and inter-disciplinary.
- Reviews work experience requests and agrees a timetable for work experience students.
- Documents feedback from external training courses attended by member of the forum.

Membership

Laboratory Manager Representative
Pathology Quality and Customer Engagement Manager
Microbiology Staff Representative
Cellular Pathology Staff Representative
Blood Sciences Staff Representative
Mortuary Staff Representative
Phlebotomy Staff Representative
Specimen Reception Staff Representative

6.4 Pathology IT Meeting (5.10.3)

The Pathology IT meetings are scheduled to meet a minimum of ten times per year.

Function

The Pathology Training Forum is a consultative committee that discusses training requirements, training plans and other issues relating to training across Pathology.

The Forum:

- Discusses and reviews IT needs across Pathology, both departmental and inter-disciplinary.

Membership

Departmental Clinical Lead Consultant(s)
Pathology Clinical Applications Specialist
Pathology Quality and Customer Engagement Manager
Laboratory Manager Representative
Microbiology Staff Representative
Cellular Pathology Staff Representative
Blood Sciences Staff Representative

Representation may be invited from:
Trust IT Applications Specialists
Third party suppliers

6.5 Pathology Quality Working Group (4.1.2.4 & 4.2)

This group is scheduled to meet once a week.
Function

The Pathology Quality Working Group meets to discuss quality activities within Pathology to ensure that each laboratory is working towards compliance with ISO 15189:2012 and maintaining compliance with MHRA, HSE and HTA. The Pathology Quality Working Group discusses the quality management system of the Pathology departments, and records and monitors progress of activities partaken using an action tracker.

The group reports to the Pathology Management Committee [PAT-P-008].

Membership

Pathology Quality & Customer Engagement Manager
Pathology Departmental Managers

6.6 Department Management Meetings

Department Management Meetings are scheduled to meet as per Terms of Reference. The following Department Management Meetings are held:

- Blood Sciences Quality Meeting
- Microbiology Management Committee
- Cellular Pathology Senior Departmental Meeting
- Mortuary Management Meeting

Function

Department Management Meetings are operational committees monitoring service provision, implementation and progress of plans, including any impediments and resource challenges. The Forums:

- Formulate and monitor the annual business plan
- Receive and act on reports from Finance, Quality Management, Health & Safety and Human Resources
- Receive, review and act on the monthly budget report
- Receive, review and act on the monthly operational report
- Review and ratify departmental policies and procedures
- Review and act on the directorate policies
- Implement and monitor progress on service improvement projects
- Review and act on IR1s, NCNs, and user complaints

Membership

Each Discipline’s Department Management Meeting consists of appropriate clinical representation and other key members of staff.

6.7 Departmental Staff Meetings

The following Department Staff Meetings are held:

- Biochemistry
• Haematology
• Specimen Reception
• Microbiology
• Cellular Pathology
• Mortuary and Bereavement Services

Function

Department Staff Meetings are the forum in which the following is cascaded to, and/or discussed with the staff group:

• IQA and EQA performance
• Departmental procedural / developmental issues
• Departmental health & safety issues
• Departmental equipment requirements
• Departmental staffing issues
• Staff training issues
• Staff Suggestions
• Effectiveness of the Quality Management System and compliance with accreditation standards

Membership

Each Discipline’s Staff Meeting consists of appropriate clinical representation and all departmental staff.
7 MANAGEMENT REQUIREMENTS

7.1 Organisation and Management (4)

The organisation and management of the Pathology Directorate is detailed under the section entitled “Organisation, Responsibilities and Authorities” in this quality manual.

7.2 Needs and Requirements of Users (4.1.2.2)

Pathology pro-actively engages with its users to ensure that the service provided continues to meet the needs and requirements of users.

The needs of the users are kept under constant review. This is achieved by:

- The Pathology Quality and Customer Engagement Manager leads on customer engagement across Pathology, liaising with service users including GWH clinicians, GPs, CCG leads and patients.
- Assessment of user satisfaction, through the use of user surveys, pro-active user engagement meetings and receipt of compliments, complaints and comments via both formal and informal routes.
- The assessment of user satisfaction through participation on professional working groups such as the Hospital Transfusion Committee and Infection Control Committee.
- Reports on assessment of user satisfaction obtained through external audits and assessments, for example Trust inspection by the Care and Quality Commission (CQC), other NHS and private healthcare providers.

The needs of the users are translated into requirements, which form the focus of objective setting and planning (4.1.2.4) within the quality management system. Assessment of user satisfaction and complaints (4.8) is conducted on a regular basis and consideration of the findings form part of the annual management review (4.12 & 4.15).

Laboratory management have established procedures for Pathology user engagement including management of complaints [PAT-Q-042].

7.3 Ethical Conduct (4.1.1.3)

Pathology follows procedures set out in the Trust Fraud and Corruption Policy [PAT-EX-077] to ensure that there is no involvement in any activity that would diminish confidence in the laboratory’s competence, impartiality, judgement or operational integrity. It is expected that all employees must be impartial and honest in the conduct of their business and remain above suspicion whilst carrying out their role within the Trust (Code of Conduct for Employees (Declarations of Interest Policy) [PAT-EX-225].

Confidentiality of information is maintained in accordance with Trust Code of Conduct in Respect of Confidentiality Policy [PAT-EX-189]. Any potential conflicts or noncompliance must be first reported to line management in accordance with the Trust Conduct Management Policy [PAT-EX-175].

All staff are required to complete Trust mandatory training. This is evidenced on an individual’s Training Tracker record. Laboratory Managers are notified of staff mandatory training status [PAT-EX-221].

Procedures are followed to ensure that human samples, tissues or remains are maintained in accordance with legal requirements. This is discussed in section 14.2 of this document.
7.4  **Quality Policy (4.1.2.3)**

The Quality Policy [PAT-P-012] of the Pathology Department is detailed on page 10 of this quality manual.

7.5  **Quality Management System (4.2)**

The components and relationship within the Quality Management System are described on page 9 of this Quality Manual.

7.6  **Quality Objectives and Plans (4.1.2.4)**

Output from the Pathology Annual Management Review identifies opportunities across Pathology for improvement of the effectiveness of the QMS and its processes, and improvement of services to users, with associated resource needs.

Annual Quality Objectives which are measurable and consistent with the Quality Policy are established and agreed in the forum of the Pathology Management Committee Annual Review meeting. Progress in achieving Quality Objectives and interim planned deadlines is reviewed at scheduled Pathology Management Committee meetings [PAT-P-008] to ensure that actions arising from management review are completed within a defined timeframe. Quality Objectives are additionally reviewed when changes to the QMS are planned and implemented to ensure that the integrity of the QMS is maintained.

Laboratory management have established procedures for Continual Quality Improvement [PAT-Q-021].

7.7  **Quality Manual (4.2.2.2)**

This standard is fulfilled by the production of this Quality Manual [PAT-Q-003].

7.8  **Quality Manager (4.1.2.7)**

The Pathology Quality and Customer Engagement Manager works with the Laboratory Management Committee/Team to ensure the proper running of the Quality Management System.

7.9  **Document Control (4.3)**

The Pathology Department utilises Q-pulse software as its procedure for document control. The QMS incorporates numerous documents, including SOPs, policies, COSHH assessments, bench guides and risk assessments. The process for creating, controlling, and managing these documents is defined in Document Control [PAT-S-001].

7.10 **External Services and Supplies (4.6)**

The Pathology Department has a documented procedure for the selection and purchasing of external services including that for equipment, reagents and consumables relevant to the quality of scope of service [PAT-S-002].
7.11 **Control of Process and Quality Records (4.13)**

The Pathology Department has a documented procedure for Control of Process and Quality Records [PAT-S-005].

These procedures include:

a) Identification and indexing  
b) Security  
c) Retention  
d) Storage and retrieval  
e) Disposal  
f) Compliance with Blood safety and quality regulations (2005).

7.12 **Control of Clinical Material (5.4.6, 5.4.7, 5.7.2 & 5.7.3)**

Laboratory management have established procedures for controlling clinical material [PAT-S-006].

7.13 **Management Review (4.12 & 4.15)**

The Pathology departments participate in an annual service review of the QMS, to ensure its continuing suitability, adequacy and effectiveness and support of patient care, and to identify any changes necessary to meet the needs and requirements of users and establish strategic plans for the forthcoming year.

The Laboratory departments conduct an annual review, the content of which is detailed in the Pathology Annual Management Review Committee Terms of Reference [PAT-P-007].

Records are kept and key objectives for subsequent years defined and plans formulated for their implementation. Quality objectives are reviewed at scheduled Pathology Management Committee meetings [PAT-P-008] to ensure that actions arising from management review are completed within a defined timeframe.
8 PERSONNEL

8.1 Staffing (5.1)

Staff records are available from the appropriate Laboratory Managers within each department or the Divisional Manager and/or Clinical Leads as appropriate. Hard copy staff records are held locally by the Department Leads and some records are held on the Organisation’s Electronic Staff Record (ESR).

The Department of Human Resources maintains the records relating to previous employment history, terms and conditions of employment, and records of disciplinary actions. The Occupational Health department maintains all the confidential medical records, including vaccinations and pre-employment checks. The Finance department maintains all records relating to salaries and wages.

The Pathology Department ensures that there are appropriate numbers of staff, with the required education and training to meet the demands of the service and appropriate national legislation/regulations (5.1.2). Registration of staff is in accordance with current national legislation and regulations: checks on the maintenance of active registration are performed in accordance with the Trust Checking and Maintenance of Professional Registration Policy and Procedure [PAT-EX-019].

Staffing includes one or more individuals with the following roles (4.1.2.5):

- Pathology Quality and Customer Engagement Manager (4.1.2.1f & 4.1.2.7)
- Pathology IT Applications Specialist
- Laboratory Managers:
  - Blood Sciences
  - Microbiology
  - Cellular Pathology
- Discipline specific Training Officers:
  - Blood Sciences
  - Microbiology
  - Cellular Pathology
- Discipline specific Health & Safety Officers:
  - Blood Sciences
  - Microbiology
  - Cellular Pathology
- Discipline specific Quality Leads:
  - Blood Sciences
  - Microbiology
  - Cellular Pathology

8.2 Personnel Management (5.1.1)

The Division has a Human Resources Business Partner assigned by the organisation, and the Pathology Department has a Human Resources Employee Relations Advisor assigned by the organisation, to assist with personnel management. The Pathology Department complies with all Human Resources policies laid down by the organisation. The organisation reviews these policies regularly and all Personnel draft policies must be approved by the organisation Policy Group prior to implementation.

The Pathology departments, through the Organisation’s Human Resources department, have procedures for:
8.2.1  Staff Orientation and Induction (5.1.4)

Staff induction is performed in accordance with the Trust Induction Policy [PAT-EX-014].

All staff are required to attend a one-day induction session on the first day of employment which is additional to local induction within the Pathology Department. Induction to the Pathology Department occurs on the second day of employment when the Trust Local Induction Checklist [PAT-EX-210] is completed. Local guidelines for specific induction within the Pathology Department not covered in the Trust Induction Policy can be found in individual departments. Induction records are filed in individual personal records, which are held by the Laboratory Manager.

The induction process includes information in accordance with the Directorate’s policy on staff orientation and induction:

8.2.2  Job Description and Contracts (5.1.3)

The Pathology department has job descriptions for all grades of staff that describe responsibilities, authorities and tasks for all personnel. The format of the documents is in accordance with the Trust templates available on the Trust Intranet pages.

These are reviewed annually at appraisal and records are kept in individual personal records. All staff are issued with a contract of employment on entering service and copies are kept centrally in the Organisation’s Personnel department as well as in the personal records held by the Lead Biomedical Scientist of the department.

8.2.3  Personal Appraisal Development Review (5.1.7)

The Pathology department conducts annual appraisal for all members of staff in accordance with the Appraisal Policy [PAT-EX-219] and Medical and Dental Revalidation and Appraisal Policy [PAT-EX-220]. Annual appraisal considers the needs of the Pathology department and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.

Appraisals are undertaken using a cascade schedule. Records of staff appraisals are kept with the Laboratory Manager. Senior members of staff who have received Trust appraisal training, conduct the appraisals. Appraisers are required to provide staff with appropriate paperwork and notice prior to the appraisal itself. Staff are encouraged to attend the Trust course entitled Receiving An Appraisal.

8.2.4  Personal Files and Staff Records (5.1.9)

All staff records are confidential and abide by the Trust Records Management Policy [PAT-EX-150].

The Laboratory Managers maintain staff records for the department in the form of personal files. The Laboratory Managers maintains records of relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel. The Department of Human Resources maintains records relating to previous employment history, terms and conditions of employment, and records of disciplinary actions. The Occupational Health department maintains all the confidential medical records, including vaccinations and pre-employment checks. The Finance department maintains all records relating to salaries and wages.
8.2.5 **Staff Meetings and Communication (4.1.2.6)**

There are regular discipline and site specific meetings open to all staff providing the opportunity for exchange of information including staff suggestions, as described in Section 6. Minutes of these meetings are kept and made available to staff.

Local communications between the Division and all departments are made through regular, Divisional and staff meetings. Divisional meetings include monthly Divisional Board meetings attended by Laboratory Managers and weekly Senior Ops meetings attended by the Head of Pathology & Imaging and Laboratory Managers as appropriate. Minutes of these meetings are kept and made available to staff.

Communications between the organisation and the Division are maintained by the following mechanisms:

- Chief Executives open forums
- The organisation Intranet
- Trust e-mail facilities
- ‘You say we did’ (staff suggestions)

8.2.6 **Staff Training and Education (5.1.5 & 5.1.8)**

Staff have access to education and training commensurate with their needs and position in the organisation. Each Pathology department has a designated Training Officer.

Training plans are identified at annual appraisal and feed into an individual’s personal development plan. The training programme has been designed in accordance with guidelines from the Health Care Professions Council (HCPC) and the Institute of Biomedical Science (IBMS). The training programme is in accordance with the Trust Continuing Professional Development Policy [PAT-EX-202].

All trainee staff have a designated supervisor and personnel undergoing training are supervised as appropriate at all times during their training period. The organisation has dedicated resources to provide education and continual professional development for training and trained staff. There are comprehensive library facilities within the organisation, and staff have access to the Internet for scientific information, a quiet room for private study, attendance at meetings and conferences and financial support. Training records are kept in personal files within the departments (5.1.9). CPD activities of the BMS staff and Consultant staff are maintained individually. The effectiveness of training programmes are periodically reviewed. There is a mechanism in place for ongoing assessment of staff competency (5.1.6).

Each discipline ensures that there is a training and education programme for all members of staff which includes the following areas (5.1.5):

a) The quality management system  
b) Assigned work processes and procedures  
c) The laboratory information system  
d) Health and safety, including the prevention or containment of the effects of adverse incidents  
e) Ethics and confidentiality of patient information
Trust Statutory and Mandatory training requirements are provided at Trust induction and annual training is received thereafter in accordance with the Trust Mandatory Training Policy [PAT-EX-221]. Each member of staff has a responsibility to ensure that their Mandatory training requirements remain current. Statutory and Mandatory training records are maintained by the Trust Academy and compliance is reported and monitored in the Quality Report presented at monthly Divisional Board meetings.
9 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS (5.2)

The Trust provides enough space and facilities to perform its laboratory and POCT activities safely and effectively in line with national legislation and guidance. There are separate areas for use of equipment and specimen reception. Incompatible activities are always separated. There are facilities for staff, patients and for storage. Access to the premises is restricted to authorised personnel by the use of the Kerri Card System. Access to and use of areas affecting the quality of the tests is controlled. There are enough telephone, bleep and e-mail communication facilities for users.

9.1 Health and Safety (5.2.1)

It is the organisation’s policy to provide and maintain a healthy and safe working environment for all our employees and visitors to the laboratory in accordance with current safety guidelines and legislation. The term “visitors” includes staff of the organisation undertaking their normal duties, those delivering goods, contractors, company representatives, other visiting professional groups, patients bringing samples, having samples taken or visiting Consultants.

The Division complies with the organisation’s Health and Safety Policy [PAT-EX-047]. The Pathology departments comply with Pathology Health and Safety Policies and Guidelines [PAT-P-015].

9.2 Staff Responsibilities for Health and Safety (5.1.5d)

Staff are made aware of their responsibilities for Health and Safety in:

- Contract of employment
- Organisation mandatory induction training (5.1.4)
- Pathology local induction training (5.1.4)
- Job descriptions

The organisation has health and safety procedures that cover:

- Storage and disposal of waste [PAT-EX-198]
- Specimen transportation procedures [PAT-EX-137]
- Control of Substances Hazardous to Health (COSHH) [PAT-EX-025]
- Display screen equipment [PAT-EX-160]
- Fire safety [PAT-EX-149]
- First aid at work [PAT-EX-161]
- Trust Health and Safety [PAT-EX-047]
- Incident management [PAT-EX-101]
- Lone workers [PAT-EX-162]
- Manual handling [PAT-EX-163]
- Minimising violence in the workplace [PAT-EX-050]
- How to assess risk [PAT-EX-145]
- Employee immunisation and screening [PAT-EX-164]
- Young persons Health and Safety at work [PAT-EX-165]
- Incident response plan [PAT-EX-203]
- Security Policy [PAT-EX-174]
- Standard infection control precautions and policy [PAT-EX-200] and associated documents
Laboratory containment facilities conform to the requirements of the Advisory Committee on Dangerous Pathogens (ACDP) guidelines on the containment of hazardous pathogens and agents and regulations on radioactivity. The Pathology departments will:

- Provide and maintain healthy and safe working conditions in accordance with the statutory requirements.
- Provide safety training as part of job induction together with special training where appropriate. Records will be kept of training.
- Provide safety equipment, protective devices and protective clothing as necessary and will ensure that they are used in an appropriate manner.
- Investigate all accidents and possible health hazards, taking appropriate action where necessary.
- Set an example of safe behaviour in all activities.
- Stimulate an interest among all our staff in all aspects of safe working practices and procedures.
- Ensure risk assessments are undertaken and necessary actions are taken to establish safe and proper working practice.
- When instrumentation or methodology is changed ensure that the risk assessments are updated.
- Ensure visitors are escorted at all times.
- Ensure in the event of evacuation, visitors are under the care of a member of staff.
- In the event of illness visitors are seen by a member of the laboratory’s medical staff and if need be, referred to the A & E department via the ambulance service.
- If any accidents or incidents occur, they are reported and fully investigated.
- Each department is subject to local Health and Safety inspection managed by the laboratory Health and Safety group. Inspection includes standards of cleanliness and housekeeping.

### 9.3 Occupational Health

The Organisation provides on-site occupational health facilities for staff. The Occupational Health Service aims to promote and maintain the highest possible level of physical, mental and social wellbeing of all employees, with the emphasis being placed on the prevention of illness.
10 LABORATORY EQUIPMENT, REAGENTS AND CONSUMABLES (5.3)

10.1 Management of Equipment (5.3.1)

The organisation has a programme for the replacement of equipment detailed in an annual plan that identifies the new and replacement equipment requirements, ensuring quality and capacity is addressed, as defined in the Trust Equipment Asset Management Procedure [PAT-EX-152].

The Pathology Department complies with national guidelines and the organisation policy on purchase, installation, training and safe disposal of all equipment, as defined in the Trust Equipment purchasing procedure [PAT-EX-151]. The Pathology Department procedure for the selection and purchasing of equipment is defined in Selection and purchasing of external services, equipment, reagents and consumable supplies [PAT-P-027]. Equipment management procedures are detailed in individual Pathology department procedures. The Trust policy ensures compliance with national legislation for:

- Fair competitive tendering
- Value for money
- Suitability and ease of use

Laboratory staff shall only be permitted to use a particular item of equipment unsupervised when the appropriate senior member of staff has established that they are competent to do so. This shall then be documented accordingly in the individual’s training record.

An inventory of equipment (5.3.1.7) is held by the departmental Lead Biomedical Scientist on each site and includes:

- The asset number of equipment (over £5k in value).
- The identity of the equipment
- Location of the equipment
- Serial number
- Date of purchase, date of entering into service and disposal
- Condition when received (new, used or reconditioned)
- Contact details for the supplier or manufacturer
- Manufacturer’s instructions
- Verification records for when equipment is incorporated into the laboratory.
- Equipment performance records confirming equipment’s ongoing acceptability for use
- Record of maintenance
- Damage to, malfunction, modification or repair of the equipment

Electrical safety checks are carried out on a regular basis by the organisation’s maintenance staff and all equipment is marked, identifying the last inspection date and when the next inspection is due. Equipment is regularly maintained through a maintenance contract with outside engineers who at minimum follow manufacturer’s recommendations.

Where it is necessary for new equipment to be commissioned and/or calibrated prior to use, this shall be carried out either in-house or through the relevant body as appropriate, in accordance with Verification of analysers and/or systems and test kit/reagents [PAT-S-007]. Manufacturer’s operating and maintenance manuals are held in the relevant section of the individual Pathology departments. Where necessary the manufacturer’s manuals are supplemented by documented in-
house methods with information pertaining to the operation, maintenance and calibration of such equipment. These can be found within procedure manuals located within the individual Pathology departments.

The Laboratory Manager of each Pathology department holds maintenance records for equipment on service contracts. The Laboratory Manager of each Pathology department holds records and certificates pertaining to the calibration of equipment.

10.2 Management of Laboratory Reagents and Consumables (5.3.2)

The Pathology department ensures the funding and availability of adequate and suitable materials required for providing a quality service to users (5.3.2). The Pathology Department procedure for the selection and purchasing of materials is defined in Selection and purchasing of external services, equipment, reagents and consumable supplies [PAT-P-027].

The assessment of suppliers is made according to standard NHS requirements for suppliers and the ability of suppliers to supply materials in accordance with the Pathology departments’ requirements. The Pathology departments aim to use those suppliers with an evidenced commitment to quality management, such as ISO 9000. All in vitro diagnostic (IVD) medical device manufacturers must comply with the requirements of the IVD Directive 98/79/EC (CE marking). All materials must be used in accordance with the manufacturers’ instructions for use. Where materials have been modified or developed in-house they are validated in accordance with Validation of Examination Procedures (5.5.1.3).

The individual Pathology Departments manage reagents and consumables in accordance with their local materials management procedures, which include:

- Ongoing acceptance for use
- Transportation, reception and storage
- Health and safety
- Inventory management
- Instructions for use
- Adverse incident reporting
- Records pertaining to materials

Materials in use are identified with date of receipt, date of first use, lot numbers and expiry dates (5.3.2.7). Additional information also includes identity of reagent, manufacturer name, contact information of supplier, condition when received and manufacturer instructions where appropriate.

The Pathology departments complete risk assessments for the use of materials in accordance with the Trust Risk Management Strategy [PAT-EX-027] and Trust How to Assess Risk Policy and Procedure [PAT-EX-145]. Risk assessments for the use of materials are included as part of the Pathology departments procedural risk assessments. The Pathology departments complete COSHH assessments for all materials in accordance with the Control of Substances Hazardous to Health Regulations 2002 and Trust policy Control of Substances Hazardous to Health (COSHH) [PAT-EX-025].

Materials which require specific disposal arrangements have the detail included in the COSHH assessment.
11 MANAGEMENT OF DATA AND INFORMATION (5.10)

Data and information is controlled and managed within the Pathology departments under the guidance of the organisation. All data and information is handled in accordance with the Trust’s governance and data protection policies which incorporate current national legislation and regulations such as the Data Protection Act (1998), the Department of Health Confidentiality NHS Code of Practice, Department of Health Security Management NHS Code of Practise and The Freedom of Information Act and Caldicott guidelines (5.10.3c) as listed below:

- Information Governance Strategy and Policy [PAT-EX-188]
- Information Protection and Security Policy [PAT-EX-156]
- Information Asset Register Procedure [PAT-EX-182]
- Data Protection Policy [PAT-EX-153]
- Data Transfer Policy [PAT-EX-186]
- Data Quality Policy [PAT-EX-187]
- Code of Conduct for Employees in Respect of Confidentiality Policy [PAT-EX-189]

The Pathology departments are subject to six-monthly audit of Information Governance compliance at departmental level in accordance with the Trust Information Governance Strategy and Policy [PAT-EX-188].

Access to electronic data is controlled and restricted through individual password security and assigned privilege rights (5.10.2) as defined in the Pathology Information Management Policy [PAT-P-013]. Server backup and periodic recovery testing is performed as defined in the Pathology Information Management Policy.

The Trust provides Statutory and Mandatory training requirements for all staff which includes Information Governance and Record Keeping. Statutory and Mandatory training records are maintained by the Trust Academy and compliance is reported and monitored in the Quality Report presented at monthly Divisional Board meetings.

Request form information may additionally be used for billing purposes, financial audit, resource management and utilization reviews.
12 PRE-EXAMINATION PROCESSES (5.4)

12.1 Information for Users and Patients (5.4.2)

The Pathology departments provide information for patients and users of the laboratory services in their individual departmental handbooks. The handbook contains general information on:

- The location of the laboratory
- Types of clinical services offered by the laboratory, including examinations referred to other laboratories
- Opening hours
- Availability of clinical advice on ordering of examinations and interpretation of examination results
- Examinations offered by the laboratory, which incorporate:
  - Sample collection containers and volumes
  - Sample collection instructions, specimen and storage transport requirements, and any special requirements
  - Information regarding test performed, measurement units, biological reference intervals, clinical decision values, result turnaround times, factors known to significantly affect results and availability as appropriate
- Instructions for completion of the request form
- Instructions for preparation of the patient
- Instructions for patient collected samples
- Requirements for patient consent
- Laboratory’s criteria for accepting and rejecting samples
- Laboratory’s policy on protection of personal information
- Laboratory’s complaint procedure

The handbooks exist online on the Trust Intranet and Trust Extranet (available to GPs) and are subject to periodic review.

Information for patients is available through the resource Lab Tests Online (www.labtestsonline.org.uk) and/or written instructions, including an explanation of any clinical procedure performed and instructions regarding preparation for the procedure.

12.2 Request Form (5.4.3)

Request forms are designed to ensure the capture of all relevant information required to provide a safe and meaningful report.

Requests forms may be generated electronically using (ICE) order-comms where available, or through completion of the appropriate paper request form. Where ICE requesting is not available paper request forms must be used.

12.3 Specimen Collection and Handling (5.4.4)

There are departmental procedures laid down for specimen collection and handling, which include Phlebotomy Sample Requirements [PHI-S-002] and Specimen Reception procedures.
The Pathology departments provide information for patients and users of the specimen collection and handling requirements in their individual departmental handbooks, which include instructions for pre-collection and collection activities.

There are specific Mortuary procedures governed by the Human Tissue Act relating to specimen collection during a post mortem, specimen disposal and specimen retention.

12.4 Specimen Transportation (5.4.5)

The procedures for transportation of samples to the Pathology laboratory’s, from internal and external collections areas, is detailed in the Trust Specimen Transportation Procedure [PAT-EX-137]. The procedure meets regulatory requirements to ensure the health and safety requirements of the carrier, the general public and the receiving laboratory.

The Pathology departments provide information for patients and users of specimen transportation requirements in their individual departmental handbooks.

The Pathology departments periodically review the transportation of samples to ensure they are transported [PAT-S-011]:

- Within the timeframe appropriate to the nature of the requested examinations
- Within a temperature interval specified for sample collection and handling
- In a manner that ensures the integrity of the sample and the safety of the carrier, the general public and the receiving laboratory

12.5 Specimen Reception (5.4.6)

The Pathology departments have procedures for specimen reception to ensure:

- Samples are unequivocally traceable by request and labelling to identified patient or site
- Criteria for acceptance or rejection of samples are applied
- Test requirements are accurately booked into the IT system
- Date and time of receipt and/or registration of samples is recorded on to the IT system
- Account is taken of urgency

All Pathology samples arrive at a central point in Pathology Reception.

Samples thought to constitute a risk to laboratory staff because of inadequate packaging or warning may be rejected.

12.6 Urgent Samples (5.4.6f)

The Pathology departments have individual documented processes for the receipt, labelling, processing and reporting of urgent samples. Urgent specimen requests arriving without notice may not be treated urgently but will be given priority. Merely marking the request form as urgent will not guarantee that the specimen is treated urgently.

Urgent samples shall take priority and will be processed and reported upon as soon as possible. Ward and outpatient areas have electronic means of accessing results. There are also specific departmental policies relating to telephoning results where necessary.
12.7 Referrals to Other Laboratories (4.5)

The Pathology departments refer a range of specialist testing to referral laboratories and Consultants. The Pathology department policy for the selection and evaluation of referral laboratories and Consultants is detailed in Examination by referral laboratories [PAT-P-023].

The Pathology departments have individual documented processes for the use of referral laboratories and Consultants which include:

- Recording the tests referred
- Documenting the results of referrals
- A record of all laboratories used in the referral of samples

Referred tests are indicated within individual departmental handbooks which contains general information on:

- Tests offered
- Name and location of the testing laboratory
- Information regarding any special sample requirements

Periodic review and evaluation of the arrangements with referral laboratories and Consultants occurs through a number of mechanisms including:

- Review of accreditation status of referral laboratories
- SLA/contract review, where such arrangements exist
- Review of turnaround time
- Review of nonconformities
13 EXAMINATION PROCESSES (5.5)

13.1 Selection, Verification and Validation of Examination Procedures (5.5.1)

The Pathology departments select, validate and verify its examination procedures in accordance with the Trust Equipment Purchasing Procedure [PAT-EX-151] and Pathology department procedure Selection and purchasing of external services, equipment, reagents and consumable supplies [PAT-P-027].

Purchasing of external services, equipment and materials follows established change control procedures as defined in Pathology Change Control [PAT-P-026].

13.2 Documentation of Examination Procedures (5.5.3)

Procedures for all examinations are documented and made available to laboratory staff in appropriate locations in accordance with the Pathology policy Document Control Procedures [PAT-S-001].

Procedures for examinations include all documents associated with the performance of examinations encompassing standard operating procedures (SOPs), summary documents (bench guides) and manufacturers’ instructions for use or user manuals.

13.3 Interlaboratory Comparisons (5.6.3)

The Pathology departments participate in all external quality assessment (EQA) (proficiency testing) schemes appropriate to the laboratory test repertoire and interpretations of examination results where such schemes are available (5.6.3.1).

The Pathology departments subscribe to EQA schemes which substantially fulfil the requirements of ISO/IEC 17043, including United Kingdom National External Quality Assessment Service (UK NEQAS) and RIQAS Global EQA scheme. Where an EQA scheme is not available the Pathology departments have developed alternative approaches for determining the acceptability of examination results (5.6.3.2).

The procedure for interlaboratory comparisons is detailed in Continual Quality Improvement [PAT-Q-021].
14 POST EXAMINATION PROCESSES (5.7)

14.1 Review of Results (5.7.1)

The Pathology departments have individual documented processes for the review of examination results before release which include the automatic selection and reporting of results.

14.2 Storage, Retention and Disposal of Clinical Samples

The Pathology departments store, retain and dispose of clinical samples in accordance with the requirements of the Human Tissue Act 2004, guidance from the Royal College of Pathologists and the Institute of Biomedical Science regarding the Retention & Storage of Pathological Records and Archives, guidance from the Royal College of Pathologists and the Institute of Biomedical Science regarding the Release of Specimens.

The Pathology document Control of Clinical Material [PAT-S-006] details the procedure for the identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.
15 REPORTING AND RELEASE OF RESULTS (4.7, 5.8, 5.9)

The laboratory aims to ensure that all reports, in hardcopy and electronic formats, are reported accurately, clearly and unambiguously in accordance with any specific instructions in the relevant examination procedures.

The Pathology departments have individual documented processes for the reporting of results which include:

- The report
- The telephoned report
- Revised reports (5.9.3)
- Clinical advice and interpretation (4.7)

15.1 Clinical Advice and Interpretation (4.7)

The Pathology departments ensure that advice on investigations and the interpretation of results meets the needs of the users and patients. The Pathology departments ensure that users have access to laboratory advice at all times. The Pathology departments ensure that all comments are clear, succinct, unambiguous and relevant to the user in the treatment of the patient.

The Pathology departments ensure that there is systematic communication between laboratory staff and clinical staff to promote effective utilisation of laboratory services and to consult on scientific and logistic matters. Where appropriate, records are kept of such meetings.
16 EVALUATION AND AUDITS, INCLUDING THE IDENTIFICATION AND CONTROL OF NONCONFORMITIES (4.8, 4.9 & 4.14)

16.1 Assessment of User Feedback and Complaints (4.8, 4.14.3)

The Pathology departments are committed to processes for user engagement including the management of complaints and other feedback received, from clinicians, patients and other parties.

Complaints and other feedback may be raised by clinicians using the Pathology service through a number of routes. These include directly to laboratory management (via e-mail, telephone, letter or face to face), feedback from user engagement assessments and the Trust incident reporting system (IR1).

The laboratories investigate all complaints received from all users and any anomalies identified relating to the laboratory’s accredited activities in accordance with the Trust Complaints Policy and Procedure [PAT-EX-028] and Pathology User Engagement Policy, including management of complaints [PAT-Q-042]. All complaints from patients are registered with PALS and logged on iCasework and are managed as per the Trust Complaints Policy and Procedure [PAT-EX-028]. IR1s are dealt with in accordance with the Trust Risk Management Strategy [PAT-EX-027] and Identification and control of nonconformities, corrective action and preventive action [PAT-S-003].

All complaints and feedback from other parties are recorded by raising a nonconformity on Q-pulse to ensure that records are maintained of all complaints, their investigation and actions taken to resolve.

Complaints and other feedback, including trends and impact, are reviewed at departmental level detailed in Identification and control of nonconformities, corrective action and preventive action [PAT-S-003].

16.2 Staff Suggestions (4.14.4)

Laboratory management actively encourages all staff to make suggestions for the improvement of any aspect of the laboratory service, ranging from service improvement initiatives to workplace improvement initiatives. This procedure is detailed in Continual Quality Improvement [PAT-Q-021]. Suggestions are evaluated, implemented as appropriate and feedback is provided to the staff. Records of suggestions and action taken by Laboratory management vary per discipline as detailed below.

Staff suggestions are evaluated and reviewed at the Pathology Management Committee Annual Review meeting for causes of nonconformities, trends and patterns that indicate process problems.

16.3 Internal Audit of Quality Management Systems (4.14.5)

The Pathology departments conduct periodic internal audits to:

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

This procedure is detailed in Internal Audit Procedures [PAT-Q-004].
The Pathology departments select auditors where resources permit that are independent of the activity being audited. Audits should be carried out by auditors appropriately trained to assess the performance of managerial and technical processes of the QMS.

It is the responsibility of the Laboratory Manager of the area being audited to ensure that appropriate action is promptly undertaken when nonconformities are identified in accordance with the SOP Identification and Control of Nonconformities, Corrective Action and Preventive Action [PAT-S-003].

16.4 Risk Management (4.14.6)

The Pathology departments evaluate the impact of work processes and potential failures on examination results as they affect patient safety in accordance with the Trust Risk Management Strategy [PAT-EX-027]. This evaluation occurs within the forum of scheduled Pathology Management Committee meetings and risks are escalated into the Divisional and Trust risk governance structure, in accordance with the document Divisional Procedure Risk Register Entries [PAT-EX-204], as appropriate for reporting and management.

Risks are recorded and managed through the Trust risk register governance structure using the Trust’s Safeguard system. Open risks are reviewed at scheduled Pathology Management Committee meetings. Risk Register entries are reviewed at Divisional weekly Senior Ops and monthly Board meetings. All risks that score 15 or more once confirmed by Divisional Management form part of the Trust’s 15+ Risk Register that is reviewed by Executive Committee and Trust Board.

16.5 Quality Indicators (4.14.7)

The Pathology departments have established indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes. The monitoring process is planned in regular monthly reports within individual Pathology departments as detailed in the Continual Quality Improvement procedure [PAT-Q-021].

Pathology department turnaround time performance indicators are stated and monitored in the Divisional Quality Report presented at monthly Divisional Board meetings and stated on the Division’s monthly Operational Performance Report which is reported to the Trust.

16.6 Reviews by External Organisations (4.14.8)

The Pathology departments are subject to review by a number of external organisations, including:

- Health and Safety Executive
- Institute of Biomedical Sciences
- United Kingdom Accreditation Service/Clinical Pathology Accreditation (UK) Ltd
- Medicines and Healthcare products Regulatory Agency
- Human Tissue Authority

Reviews performed by external organisations are recorded in Q-pulse and any findings from external review are managed in accordance with Identification and control of nonconformities, corrective action and preventive action [PAT-S-003].
16.7 Identification and Control of Nonconformities (4.9)

The Pathology procedure Identification and Control of Nonconformities, Corrective Action and Preventive Action [PAT-S-003] describes how nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes are identified and managed. The procedure also determines how potential nonconformities are identified and how appropriate preventive actions are agreed and implemented.
## 17 APPENDIX A

Policies established for the Pathology departments Quality Management System (4.2.2.2f):

<table>
<thead>
<tr>
<th>DCN</th>
<th>Document Title</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAT-EX-007</td>
<td>Trust Risk Management Strategy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-014</td>
<td>Trust Induction Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-019</td>
<td>Trust Checking and Maintenance of Professional Registration Policy and Procedure</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-025</td>
<td>Control of Substances Hazardous to Health (COSHH)</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-027</td>
<td>Trust Risk Management Strategy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-028</td>
<td>Trust Complaints Policy and Procedure</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-047</td>
<td>Trust Health and Safety Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-050</td>
<td>Minimising Violence in the Workplace</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-077</td>
<td>Trust Fraud and Corruption Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-101</td>
<td>Incident Management Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-137</td>
<td>Specimen Transportation Procedure</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-145</td>
<td>How to Assess Risk Policy and Procedure</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-149</td>
<td>Fire safety Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-150</td>
<td>Trust Records Management Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-151</td>
<td>Trust Equipment purchasing procedure</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-152</td>
<td>Trust Equipment Asset Management Procedure</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-153</td>
<td>Data Protection Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-156</td>
<td>Information Protection and Security Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-160</td>
<td>Display Screen Equipment Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-161</td>
<td>First Aid at Work Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-162</td>
<td>Lone Workers Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-163</td>
<td>Manual Handling Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-164</td>
<td>Employee Immunisation and Screening Guidelines</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-165</td>
<td>Young Persons Health and Safety at work Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-174</td>
<td>Security Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-175</td>
<td>Trust Conduct Management Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-182</td>
<td>Information Asset Register Procedure</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-186</td>
<td>Data Transfer Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-187</td>
<td>Data Quality Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-188</td>
<td>Information Governance Strategy and Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-189</td>
<td>Code of Conduct for Employees in Respect of Confidentiality Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-198</td>
<td>Trust Waste Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-200</td>
<td>Standard infection control precautions and policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>DCN</td>
<td>Document Title</td>
<td>Location</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>PAT-EX-202</td>
<td>Continuing Professional Development Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-203</td>
<td>Incident response plan</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-204</td>
<td>Risk Register Entries</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-210</td>
<td>Trust Local Induction Checklist</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-219</td>
<td>Appraisal Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-220</td>
<td>Medical and Dental Revalidation and Appraisal Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-221</td>
<td>Mandatory Training Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-EX-225</td>
<td>Code of Conduct for Employees (Declarations of Interest) Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-007</td>
<td>Pathology Annual Management Review Committee Terms of Reference</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-008</td>
<td>Pathology Management Committee terms of reference</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-012</td>
<td>Quality Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-013</td>
<td>Pathology Information Management Policy</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-015</td>
<td>Pathology Health and Safety Polices and Guidelines</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-023</td>
<td>Examination by referral laboratories</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-026</td>
<td>Pathology Change Control</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-P-027</td>
<td>Selection and Purchasing of External Services, Equipment, Reagents and Consumable Supplies</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-Q-003</td>
<td>Quality Manual</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-Q-004</td>
<td>Internal Audit Procedures</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-Q-021</td>
<td>Continual Quality Improvement</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-Q-042</td>
<td>Pathology User Engagement Policy, Including Management of Complaints</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-S-001</td>
<td>Document Control</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-S-003</td>
<td>Identification and Control of Nonconformities, Corrective Action and Preventive Action</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-S-005</td>
<td>Control of Process and Quality Records</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-S-006</td>
<td>Control of Clinical Material</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-S-007</td>
<td>Verification of analysers and/or systems and test kit/reagents</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PAT-S-011</td>
<td>Pathology Monitoring Procedures of Specimen Transportation</td>
<td>Q-pulse</td>
</tr>
<tr>
<td>PHL-S-002</td>
<td>Phlebotomy Sample Requirements</td>
<td>Q-pulse</td>
</tr>
</tbody>
</table>

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