PATHOLOGY SPECIALTY QUALITY MANUAL
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1 SCOPE

This quality manual (QM) along with the procedures specified in this document describes the quality management system (QMS) of the Royal Cornwall Hospitals Trust (RCHT) Pathology specialty.

This QM has been written for all Pathology staff, service users and accreditation bodies to describe the QMS within Pathology and also to meet the requirements of International Organization for Standardization (ISO) 15189:2012 and other regulatory requirements. All personnel are required to be familiar with the contents of this document and all procedures relevant to their work.

Alongside this document, there a number of generic overarching documents, all written to ISO standards [shown in square brackets] which describe the principles behind the Pathology procedure which applies to all laboratories within Pathology. These documents are maintained by the Pathology Quality and Improvement Manager (PQIM), reviewed by the departmental quality leads (QL) and approved by the specialty management team.

Each individual department is responsible for documenting local, detailed procedures which conform to the overarching Pathology strategies. Documentation is available on the Pathology service QMS tool Q-Pulse and information regarding the distribution, staff acknowledgement and review history can be found in the document control system.

This QM has been written so that each section links to a specified ISO 15189:2012 clause and are compliant to other regulatory bodies such as Human Tissue Act (HTA) and Blood safety and quality regulations (BSQR). Following each title within the QM is a brief explanation of how the Pathology service will meet the requirement and references are given for appropriate documents within the QMS.

The Pathology specialty, has adopted a system of total quality management to facilitate delivery of a high quality analytical, interpretive, advisory and consultancy service that is cost effective and meets the needs and requirements of its service users.

The core values of the QMS within Pathology include

- Patient focus
- Total employee involvement
- Quality centred processes
- Strategic and Systematic processes
- Integrated Systems
- Fact-based decision making
- Communication
- Continual improvement
- Audit

The Pathology management ensures that all staff are working in a safe environment, are highly skilled and utilise up to date technology. This is achieved by trust and internal audits, specific training and competency assessments.

Within Pathology there are a number of additional regulatory bodies and authorities which oversee areas of the service, including:
• Clinical Pathology Accreditation (CPA)/United Kingdom Accreditation Service (UKAS). The Pathology specialty is currently accredited to CPA standards and is working towards ISO15189:2012 accreditation (POCT is not currently accredited)
• Institute of Biomedical Sciences (IBMS) for biomedical scientist (BMS) training approval
• National Health Service Litigation Authority (NHSLA)
• Medicines and Healthcare Products Regulatory Agency (MHRA)
• BSQR 2005
• Care Quality Commission (CQC) - Since 2010 RCHT has been assessed in accordance with CQC standards
• Southern Quality Assurance Services (SQAS) - All NHS screening programmes
• HTA has granted a licence (12208) to the Royal Cornwall Hospital (RCH) under the Human Tissue Act 2004.
• External quality assurance schemes (EQA) and organisations specific to individual departments and testing regimes
• Her Majesty’s Coroner (HMCO)
• Public Health England (PHE)
• National Health Service Blood and Transplant (NHSBT)
• British committee for standards in Haematology (BCSH)

Each department within Pathology is responsible for their own accreditation application, inspection and any specific governing body and/or authority to which they have specific standards of compliance.

2 NORMATIVE REFERENCES
ISO17025 General Requirements for the competence of testing and calibration laboratories
UKAS TPS 41 Traceability of measurement
UKAS TPS 47 Policy on participation in proficiency testing
UKAS TPS 63 Policy on Deviating Specimens
UKAS TPS 37 Simplified Test Reports
UKAS TPS 51 Accreditation of Multi-Site/Group Laboratories
UKAS TPS 57 Guidance and Policy on the Selection and Use of Reference Materials
UKAS TPS 59 Implementation and Management of Flexible Scopes of Accreditation for the commissioning of Site Laboratories
UKAS TPS 62 Management of Extraordinary Events or Circumstances Affecting UKAS accredited Certification Bodies and their Certified Organisations


3 TERMS AND DEFINITIONS
AMR: Annual management review
Anc.: Ancillary/Admin staff
APT: Anatomical Pathology Technician
BCSH: British Committee for Standards in Haematology
BMS: Biomedical Scientist
BSQR: Blood Safety and Quality Regulations
CA/PA: Corrective Action/Preventative Action
CAP: Clinical Approval Meetings
RCHT Pathology Controlled Document
Q-Pulse Reference: PA-QMS-MAN-1
Revision: 15
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QL: Quality Lead
QMS: Quality Management System
QM: Quality Manual
Q-Pulse: Software / QMS tool
RAG: Red, Amber and Green Rating
RCA: Root Cause Analysis
RCH: Royal Cornwall Hospital
RCHT: Royal Cornwall Hospital Trust
RCPath: Royal College of Pathologists
SD: Specialty Director
SLA: Service Level Agreement
SMH: St Michael's Hospital
SOP: Standard Operating Procedure
SQAS: Southern Quality Assurance Services
TERA: Training and Education
UKAS: United Kingdom Accreditation Services
WCH: West Cornwall Hospital
Winpath: Pathology Computer System

4 DOCUMENTATION

Refer to the Related Documents section in the Q-Pulse Document Record for links to Pathology-controlled documents.

5 MANAGEMENT REQUIREMENTS (ISO Clause 4.1)

5.1 Organisation

The Pathology Service is based at RCH in Truro and is spread over the whole site (See diagram below). Services are provided to RCHT and the wider healthcare community in Cornwall, with specific services provided to the wider South West Peninsula. Although the main services are based at RCH, some services are provided at satellite sites across the Trust including West Cornwall Hospital (WCH) (Penzance), St Michael's Hospital (SMH) (Hayle), and Community hospitals across Cornwall. Detailed information on the services provided and contact telephone numbers are available in the Pathology User Guide and on the RCHT website A-Z of Services.

http://intra.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/Pathology/PathologyHandbook.pdf
The Pathology service is a specialty within the Clinical Support & Cancer Services (CSCS) directorate at RCHT.

The Pathology service is comprised of the following departments –

- Diagnostic and Molecular Pathology (DMP) – which comprises of Histopathology, Molecular Cell Biology, Cytology, Mortuary and Bereavement service
- Haematology
- Blood Transfusion
- Clinical Chemistry including Point of Care (POCT)
- Clinical Microbiology (CMB)
- Phlebotomy services

The Pathology Service Manager (PSM) contact details are:

Mr Bruce Daniel
Royal Cornwall Hospitals Trust
Clinical Microbiology
Treliske
Truro
Cornwall NHS TR1 3LJ

For RCH Board, directorate, specialty and department structures please see appendix 1

The Pathology specialty is supported by other RCHT services including estates, finance, procurement, information technology (IT), human resources (HR) and governance (please note this list is not exhaustive).
### Pathology Service Core working Hours and Out-Of-Hours Cover

<table>
<thead>
<tr>
<th></th>
<th>Clinical Chemistry</th>
<th>Haematology &amp; Blood Transfusion</th>
<th>CMB</th>
<th>DMP</th>
<th>Mortuary/Bereavement Service</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core Working Hours</strong></td>
<td>08.00 to 20.00</td>
<td>08.00 to 20.00</td>
<td>08.45 to 17.15</td>
<td>08.30 to 17.00</td>
<td>07.30 to 16.00 (Mortuary) 09.00 to 16.00 (Bereavement Service)</td>
</tr>
<tr>
<td><strong>Weekday Night</strong></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>20:00 to 08:00</td>
<td>20:00 to 08:00</td>
<td>17:15 to 08:45</td>
<td></td>
<td>HTA / Management cover</td>
</tr>
<tr>
<td></td>
<td>1 x BMS</td>
<td>1 x BMS</td>
<td>1 x BMS On-Call⁵</td>
<td></td>
<td>On-Call⁵</td>
</tr>
<tr>
<td></td>
<td>Consultant On-Call⁵</td>
<td>Consultant On-Call⁵</td>
<td>Consultant On-Call⁵</td>
<td></td>
<td>No Consultant Cover</td>
</tr>
<tr>
<td><strong>Saturday</strong></td>
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<td></td>
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<tr>
<td></td>
<td>08:00</td>
<td>08:00</td>
<td>08:30 to 12:30 Team of:</td>
<td></td>
<td>HTA / Management cover</td>
</tr>
<tr>
<td></td>
<td>MLA 08:00 to 16:00</td>
<td>MLA 08:00 to 16:00</td>
<td>3 x MLA, 1 x MLSW</td>
<td></td>
<td>On-Call⁵</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 08:00 to 20:00</td>
<td>1 x BMS 08:00 to 14:00</td>
<td>8 x BMS, 1 x Anc.</td>
<td></td>
<td>1 x BMS On-Call⁵</td>
</tr>
<tr>
<td></td>
<td>1 x Clin. 09:00 to 13:00</td>
<td>1 x BMS 08:00 to 20:00</td>
<td>1 x Consultant</td>
<td></td>
<td>Consultant On-Call⁵</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 20:00 to 08:00</td>
<td>1 x BMS 20:00 to 08:00</td>
<td>12:30 to 08:45</td>
<td></td>
<td>12:30 onwards</td>
</tr>
<tr>
<td></td>
<td>Consultant On-Call⁵</td>
<td>Consultant On-Call⁵</td>
<td>1 x BMS On-Call⁵</td>
<td></td>
<td>1 x BMS On-Call⁵</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Consultant On-Call⁵</td>
<td></td>
<td>No Consultant Cover</td>
</tr>
<tr>
<td><strong>Sunday</strong></td>
<td></td>
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<tr>
<td></td>
<td>08:00</td>
<td>08:00</td>
<td>08:30 to 12:30 Team of:</td>
<td></td>
<td>HTA / Management cover</td>
</tr>
<tr>
<td></td>
<td>MLA 08:00 to 20:00</td>
<td>MLA 08:00 to 20:00</td>
<td>2 x MLA, 1 x MLA</td>
<td></td>
<td>On-Call⁵</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 09:00 to 15:00</td>
<td>1 x BMS 09:00 to 15:00</td>
<td>Consultant On-Call⁵</td>
<td></td>
<td>1 x BMS On-Call⁵</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 20:00 to 08:00</td>
<td>1 x BMS 20:00 to 08:00</td>
<td>12:30 to 08:45</td>
<td></td>
<td>No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>Consultant On-Call⁵</td>
<td>Consultant On-Call⁵</td>
<td>1 x BMS On-Call⁵</td>
<td></td>
<td>No Consultant Cover</td>
</tr>
</tbody>
</table>

**Notes:**

1. All BMS staff who work “out-of-hours” in Clinical Chemistry and Haematology stay on-site and work continuously.
2. The start time of this session can vary between 09:00 and 10:00, ending suitably later.
3. On-Call sessions for urgent Microbiology also include four fixed hours of cover for essential work such as Blood cultures and *Clostridium difficile*.
4. Saturday morning BMS provision for Histopathology is an on-site service.
5. On-call from home for the entire period.
Key roles in Pathology

The core members of the Pathology directorate management team are:

- PSM
- Specialty Director (SD)
- Lead BMS’s (LBMS)
- Laboratory Leads
- Consultants
- Head of Departments (HOD)
- PQIM

The Pathology specialty management meeting is conducted monthly and the minutes are found on Q-Pulse within the investigation module. The meeting is supported by finance and governance departments when required. The terms of reference for the specialty management meeting were agreed and ratified in the meeting and placed on Q-Pulse for acknowledgement by all team members. Full details of the key roles and duties are found in the individual job descriptions.

Table 1.1

<table>
<thead>
<tr>
<th>Key Role</th>
<th>Name</th>
<th>Delegated duties from Speciality Director</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD</td>
<td>Dr Simon Fleming</td>
<td>The SD has responsibility for the effective leadership, operation and administration of the laboratory. The SD is accountable to the CSCS and works closely with the PSM on the strategic development and modernisation of Pathology.</td>
</tr>
<tr>
<td>PSM</td>
<td>Bruce Daniel</td>
<td>The PSM is responsible for the delivery of a safe, high quality and efficient Pathology service and works closely with the SD on the strategic development and modernisation of Pathology. The PSM is accountable to the CSCS Associate Director</td>
</tr>
<tr>
<td>HOD</td>
<td>Dr Robert Jenkins (DMP) Dr Richard Bendall (CMB) Dr Adam Forbes (Haematology/Blood Transfusion) Dr Anthea Patterson (Clinical Chemistry)</td>
<td>Leadership, communication and team working within the laboratory, providing advice to the SD and PSM on specialty issues. This includes accountability for all aspects of clinical governance, including quality assurance and accreditation, and the development of services.</td>
</tr>
</tbody>
</table>
| LBMS | Stephen Bassey  
(Blood Transfusion,  
Haematology/MHRA  
Lead)  
Peter Helliwell  
(DMP, CMB and  
HTA Lead) | Reporting to the PSM.  
Budget planning and financial management.  
Ensure compliance with regulatory agencies,  
administrative officials.  
Relate and function effectively with the healthcare  
community, patient population and production of service  
level agreements (SLA) where required.  
Ensure there are appropriate numbers of competent  
staff to meet service user requirements.  
Implementation of the quality policy.  
Implementation of a safe laboratory facilities and  
environment.  
Select and monitor laboratory suppliers.  
Monitor the service quality of referral laboratories.  
Define, implement and monitor standards of  
performance and quality improvements.  
Monitor work performed to determine clinically relevant  
information is being generated.  
Provision of professional development for laboratory  
staff.  
Address any request, complaint or suggestion from staff  
or service user.  
Design and implement contingency plans to ensure that  
esential services are available during emergency  
situations or conditions where services are limited or  
unavailable.  
HR management of staff. |
| --- | --- | --- |
| Laboratory Leads  
(*Delegation may vary  
between individuals –  
please see specific  
job descriptions for  
details) | Simone Girdham  
(Clinical  
Microbiology)  
Stephen Bassey  
(Blood Transfusion  
and Haematology)  
Alan Bromley  
(Clinical Chemistry)  
Val Rodd (DMP,  
Clinical Histology)  
Cathy Winn (DMP,  
Cytology)  
Kevin Hammett  
(DMP, Mortuary) | Reporting to the LBMS.  
Budget planning and financial management.  
Ensure compliance with regulatory agencies,  
administrative officials.  
Relate and function effectively with the healthcare  
community, patient population.  
Ensure there are appropriate numbers of competent  
staff to meet service user requirements.  
Implementation of the quality policy.  
Implementation of a safe laboratory facilities and  
environment.  
Select and monitor laboratory suppliers.  
Define, implement and monitor standards of  
performance and quality improvements.  
Address any request, complaint or suggestion from staff  
or service user.  
HR management of staff. |
| Clinical Governance  
Leads | Dr Ilona Hopkins  
(DMP)  
Dr Simon Fleming | Facilitating and documenting clinical governance issues  
and implementing service improvements for clinical  
roles and systems. |
<table>
<thead>
<tr>
<th>Role</th>
<th>Name(s)</th>
<th>Responsibilities / Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Audit Leads</td>
<td>Dr Julie Blundell (Haematology/Blood Transfusion)</td>
<td>Responsible for clinical audit schedule and submission / registration of clinical audits to the Trust clinical audit group.</td>
</tr>
<tr>
<td></td>
<td>Dr Thomas Grigor (DM)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vacant – CMB</td>
<td></td>
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<tr>
<td></td>
<td>Dr Anthea Patterson (Clinical Chemistry)</td>
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<tr>
<td>Clinical Incident investigators</td>
<td>Dr Robert Jenkins</td>
<td>Staff that have attended the Trust clinical investigator training can be assigned clinical serious and critical untoward incidents.</td>
</tr>
<tr>
<td></td>
<td>Sarah Pointon</td>
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<tr>
<td>Clinical Education Lead</td>
<td>Dr Julie Blundell (Haematology/Blood Transfusion)</td>
<td>Plan and direct research where appropriate.</td>
</tr>
<tr>
<td></td>
<td>Dr Robert Jenkins (DM)</td>
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<tr>
<td></td>
<td>Vacant – CMB</td>
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<tr>
<td></td>
<td>Dr Anthea Patterson (Clinical Chemistry)</td>
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<tr>
<td>Training officer</td>
<td>Martin Hicks (Haematology/Blood Transfusion)</td>
<td>Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations. The training officer provides advice and support to training co-ordinators and senior staff to deliver high quality and effective training. Monitors training compliance across the laboratory</td>
</tr>
<tr>
<td></td>
<td>Peter Helliwell (DM)</td>
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<td></td>
<td>Debbie Wadham (CMB)</td>
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<tr>
<td></td>
<td>Alan Bromley (Clinical Chemistry)</td>
<td></td>
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<tr>
<td>Complaints Officers</td>
<td>Martin Hicks (Haematology/Blood Transfusion)</td>
<td>Address any complaint from staff or service users.</td>
</tr>
<tr>
<td></td>
<td>Peter Helliwell/Georgina Purvis/Valerie Rodd (DM)</td>
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<tr>
<td></td>
<td>Lindsey Vincent (CMB)</td>
<td></td>
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<tr>
<td></td>
<td>Alan Bromley/Jo Walsh (Clinical Chemistry)</td>
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<tr>
<td>Human Resources (HR) Lead</td>
<td>Stephen Bassey/Martyn Hicks (Haematology/Blood Transfusion)</td>
<td>Accountable to LBMS. Advises and facilitates HR issues in accordance with Trust policies.</td>
</tr>
<tr>
<td></td>
<td>Valerie Rodd (DM)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vickie Horton-Szar (CMB)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alan Bromley/Jo Walsh (Clinical Chemistry)</td>
<td></td>
</tr>
<tr>
<td>Role</td>
<td>Person(s)</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>HR Investigators</td>
<td>Stephen Bassey/Martyn Hicks</td>
<td>Staff that have attended the Trust HR investigator training can be assigned formal HR investigations.</td>
</tr>
<tr>
<td></td>
<td>Valerie Rodd, Leonie Glinski, Georgina Purvis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vickie Horton-Szar, Alan Bromley/Jo Walsh</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathology Health and Safety (H&amp;S) Lead</td>
<td>Sarah Pointon</td>
<td>Co-ordinates and facilitates H&amp;S in accordance with regulatory bodies, Trust requirements and emergency services. Advise the directorate and specialty on H&amp;S issues.</td>
</tr>
<tr>
<td>H&amp;S Specialty Leads</td>
<td>Val Rodd (DMP), Simone Girdham (CMB), Alison Thornton (Clinical Chemistry), Ian Sullivan (Haematology/Blood Transfusion)</td>
<td>Co-ordinates and facilitates H&amp;S in accordance with regulatory bodies, Trust requirements and emergency services and ensures safe laboratory environment.</td>
</tr>
<tr>
<td>Human Tissue Authority (HTA) Designated Individual (DI)</td>
<td>Peter Helliwell (DMP)</td>
<td>Co-ordinates the implementation of the HTA guidelines. Has legal responsibility to ensure suitable practices are being undertaken, ensure conditions of the license are being complied with and that all persons working under the license are suitable.</td>
</tr>
<tr>
<td>HTA Person designated (PD) for Histology</td>
<td>Georgina Purvis, Matthew Coles, Kevin Hammett</td>
<td>Responsibilities are delegated from HTA DI. The PD’s are registered with the HTA but do not carry the legal responsibility of the DI. They are available for local advice and guidance; they provide a bridge between the DI and the researcher. The PD keeps a catalogue of human tissue samples in their area of responsibility.</td>
</tr>
<tr>
<td>Information Management and Technology (IM&amp;T) Manager</td>
<td>Don Hutchison</td>
<td>Oversee the IM&amp;T systems within Pathology including Maxims, Win Path and Q-Pulse. To supervise the Pathology IM&amp;T team. Maintain the require messaging and coding to keep the system current and efficient. To support Pathology services performance and use by providing timely data and information. To produce data files as required for Freedom of Information and Trust legal team requests.</td>
</tr>
<tr>
<td>Departmental IM&amp;T Lead</td>
<td>Matt Coles (DMP), Barrie Durrant (CMB)</td>
<td>Providing computer systems supervision, to include implementation, management and support.</td>
</tr>
<tr>
<td>Hospital Based Cervical Screening Co-ordinator</td>
<td>Cathy Wilson (DMP)</td>
<td>Oversees compliance and data submission / audit / failsafe for the NHS Cervical Cancer screening programme.</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
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<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>POCT Lead</td>
<td>Helen Hobba (Clinical Chemistry)</td>
<td>Oversee the day-to-day running of the POCT within the Trust and Community.</td>
</tr>
<tr>
<td>Downs Screening Lead</td>
<td>Dr Angela Mallard (Clinical Chemistry)</td>
<td>Oversees service performance, compliance and data submission for the Downs screening programme.</td>
</tr>
<tr>
<td>Breast Screening Lead</td>
<td>Dr Robert Jenkins (DMP)</td>
<td>Oversees compliance and data submission / audit for the NHS Breast Cancer screening programme.</td>
</tr>
<tr>
<td>Bowel Cancer screening lead</td>
<td>Dr Ilona Hopkins (DMP)</td>
<td>Oversees compliance and data submission / audit for the NHS Bowel Cancer screening programme.</td>
</tr>
<tr>
<td>PQIM</td>
<td>Sarah Pointon</td>
<td>Accountable to the PSM. Oversees the Pathology QMS, including management of risks and quality service improvements.</td>
</tr>
<tr>
<td>QL</td>
<td>Teresa Vercoe (Haematology)</td>
<td>Accountable to Laboratory Leads. Facilitates quality management within department. Oversees and maintains QMS. Advisory support for senior staff regarding QMS compliance. Implementation of processes and procedures to ensure compliance with regulatory bodies. Liaise closely with PQIM and the QL. Ensure the implementation of the quality policy.</td>
</tr>
</tbody>
</table>

| ISO Clause 4.1.1.2 |

RCHT is the legal entity of the Pathology Service located on the hospital site at Truro. RCHT will be held legally responsible for all of the activities carried out within Pathology. Confirmation can be found at [www.legislation.gov.uk](http://www.legislation.gov.uk).

The contact details of RCHT are:
RCHT
Treliske
Truro
TR1 3LJ
Telephone – 01872 250000

| ISO Clause 4.1.1.3 |

The ethical conduct expected of staff within Pathology is outlined in the Pathology acceptable standards of staff conduct standard operating procedure (SOP) [PA-GEN-SOP-28].

This document covers:
- A statement to confirm that the Pathology service has no involvement in any activities that would diminish confidence in the laboratory’s competence, impartibility, judgement or operational integrity
- Any financial, commercial or other pressures that may affect the work
- No conflicts of interest
- All specimens are dealt with according to relevant legal requirements
- Confidentiality
- BMS staff must be registered with the Health and Care Professions Council (HCPC)
- Medical staff are registered with the General Medical Council (GMC) or equivalent for overseas staff

All staff are aware of the need to formally raise concerns when they encounter or suspect wrong doing or malpractice and it would be in the public interest for these concerns to be raised. The Trust Policy Raising Concerns in the Public Interest (Whistleblowing Policy) outlines the process to be followed and quotes examples of when this may apply. These include:

- Wilful neglect which compromises H&S
- Patient abuse or neglect or ill treatment
- Unlawful or unprofessional conduct and/or performance
- Disregard of H&S rules
- Receipt of gifts or hospitality outside of Trust policy
- Conflict of interest
- Fraud or financial mismanagement

Within the Trust and local induction programmes all staff are aware of the requirement to ensure that all specimens are dealt with in accordance with UK legal requirements including compliance with environmental and waste regulations.

5.4 Laboratory Director (ISO Clause 4.1.1.4)

The Laboratory Director within Pathology is titled as Pathology SD and is also a consultant within a Pathology specialty.

The SD accepts overall responsibility for the effective delivery of services and responsibilities and duties are detailed in the job description. Delegated responsibilities / key roles are also recorded – see table 1.1. Where individuals are not named the responsibility remains with the specialty director.

The SD is supported closely by the PSM manager to ensure the effective delivery of services within Pathology.

The QMS ensures the SD is competent to perform within their role by documenting certification of qualification requirements specific to their role, continuing professional development (CPD) and participation in external quality assurance (EQA) schemes.

5.5 Management Responsibility and Commitment (ISO Clause 4.1.2 & 4.1.2.1)

The specialty management are engaged with the implementation, development and continued improvement to facilitate a total QMS throughout Pathology.

Compliance with the QMS and the requirements of the service users is communicated to laboratory personnel via –

- Structured Pathology meetings (refer to table 1.2)
- Quality training and competency
Feedback from Annual Management Review (AMR)
Quality newsletter
Feedback from service users survey

Quality objectives are set annually at the AMR. Progress is monitored quarterly by each department. Details can be found in the audit module in Q-Pulse.

5.6 Needs of users (ISO Clause 4.1.2.2)

To ensure that all laboratory services meet the needs of the service users - management facilitate and encourage participation in the following, at Pathology wide and/or directorate level:

- Service user survey (Distributed annually)
- User liaison visits, communications and user information
- Patient engagement via patient ambassadors
- Monitoring Turnaround Times
- External Quality Assurance (EQA)
- Findings from external and internal audits
- Biennial review of Pathology user Guide in consultation with user representatives
- Periodic review of SLA and contracts
- Responding to complaints raised by users and patients
- Adhoc feedback received from users and staff regarding service/result issues
- Attendance of senior Laboratory staff at Trust Divisional and specialty meetings, General Practitioner (GP) commissioning / locality group meetings and regional groups
- Strategy meetings involving the HMCO, Police and Council meetings (When requested by the HMCO)
- Comprehensive audit schedule
- Pathology Quality Group (PQG) and the departmental monthly quality template reviews, feedback from these is captured via Q-Pulse,
- Cervical screening programme sample taker training and laboratory tours
- Assistance with sample preservation and collection training (Cytology fine needle aspirations)

Needs of users are communicated to staff via specialty and staff meetings, minutes of which are available on Q-Pulse or in the shared folder on the computer system.

5.7 Quality Policy (ISO Clause 4.1.2.3)

The overall intentions of the Pathology Management are documented in the Quality Policy [PA-QMS-POL-1]. This policy is reviewed and approved annually within the AMR by the Pathology Management Team.

The Quality Policy is written as a separate controlled document and signed by the Associate Director. All Pathology staff are introduced to the policy as part of their induction and training and are required to acknowledge the document on Q-Pulse.

The document is printed off Q-Pulse and displayed within each laboratory and on the Pathology intranet site.
5.8 Quality objectives and Planning (ISO Clause 4.1.2.4, 4.12 & 4.15)

The Pathology specialty defines the quality objectives on an annual basis within the departmental and pan-Pathology AMR’s.

The objectives are agreed by the Pathology management team and progress/action plans with the previous objectives are discussed at the AMR.

Progress of these objectives within each laboratory and Pan-Pathology are reviewed quarterly and are Red Amber Green (RAG) rated to monitor progress of the objective completion (Refer to Q-Pulse audit module).

It is the individual department’s responsibility to ensure plans and actions are agreed, documented and carried out to meet these objectives.

5.9 Responsibility, authority and interrelationships (ISO Clause 4.1.2.5)

Please refer to the key roles table 1.1 for responsibilities of key roles (e.g. Lead BMS, QL, H&S Lead). These roles and responsibilities are recorded in personnel job descriptions.

Organisational structures for directorate and Pathology specialty can be found in Appendix 1.

5.10 Communication (ISO Clause 4.1.2.6)

Staff meetings and regular management meetings occur in each laboratory and active participation by all staff is encouraged. These meetings also offer opportunity for staff to raise ideas and suggest quality improvements. Minutes of the meetings are taken, recorded and distributed to staff either by paper copy, email or via Q-Pulse – Refer to Table 1.2, 1.3, 1.4, 1.5, 1.6 and 1.7

Communication to service users is achieved through a variety of mechanisms including:-

- Website
- News bulletins/newsletters
- Attendance at user meetings e.g. GP liaison visits
- User satisfaction surveys
- Resolution of complaints and incidents
- Documented policies and procedures
<table>
<thead>
<tr>
<th>Meeting</th>
<th>Frequency</th>
<th>Attendees</th>
<th>Aims</th>
<th>Minutes recording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate Management</td>
<td>Monthly</td>
<td>Associate Director (chair) PSM Pathology specialty director Directorate governance lead Directorate managers including HR, Finance and patient services Clinicians</td>
<td>To discuss monitor and progress the operational and strategic aims and activity of the Directorate</td>
<td>S:\TR13\Clinical Support Services Cancer\Meetings\Groups\DMB meetings\2016 DMB Meeting Papers</td>
</tr>
<tr>
<td>Governance Meeting</td>
<td>Monthly</td>
<td>Associate Director (chair) PSM Pathology specialty director Directorate governance lead</td>
<td>To discuss Directorate governance issues</td>
<td>S:\TR13\Clinical Support Services Cancer\Governance\Gov DMB</td>
</tr>
<tr>
<td>H&amp;S Meeting</td>
<td>Every six weeks</td>
<td>Directorate H&amp;S Lead (chair) Directorate governance lead PQIM</td>
<td>To discuss Directorate H&amp;S issues</td>
<td>S:\TR13\Clinical Support Services Cancer\Meetings\Groups\H&amp;S Group\Agenda &amp; Minutes</td>
</tr>
<tr>
<td>Meeting</td>
<td>Frequency</td>
<td>Attendees</td>
<td>Aims</td>
<td>Minutes recording</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Pathology Specialty</td>
<td>Monthly</td>
<td>PSM, Pathology specialty director, PQIM, Consultant/Clinical representative, Laboratory Leads, Staff representative</td>
<td>To discuss, confirm, review and action operational, financial governance and quality issues and reports related to the Pathology specialty</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>management meeting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PQG</td>
<td>Monthly</td>
<td>PQIM (Chair), Department QL, Laboratory Leads, PSM, Pathology IM&amp;T Manager, Consultant/Clinical representative, Additionally representatives from the following areas are invited to attend: Directorate Governance Lead</td>
<td>To discuss Pathology quality and QMS issues</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>IT</td>
<td>Bi-Monthly</td>
<td>Pathology IM&amp;T Manager (chair), Pathology IM&amp;T Team, PSM/ Deputy PSM, Department IT Leads, CITS project representative and support representative</td>
<td>To discuss Pathology IT issues</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Pathology H&amp;S Group</td>
<td>Quarterly</td>
<td>PQIM (Chair), Department H&amp;S Leads, Laboratory Leads, PSM, Consultant/Clinical representative</td>
<td>To discuss Pathology H&amp;S issues</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>AMR (all specialties)</td>
<td>Annual</td>
<td>PQIM (Chair for pan-Pathology AMR), Senior BMS / Medical Staff, departmental QIs</td>
<td>To discuss Pathology quality issues and praises in the past year</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
</tbody>
</table>

Table 1.3 Pan-Pathology
Bi-directional communication (Pathology and RCHT)

Communication filtered down from Trust Board

Communication escalated to Trust Board

Trust Governance/H&S Group

Directorate H&S Group

Directorate Governance Group via quarterly report to Governance Lead

Specialty Senior Managers meeting

PQG including AMR Pathology H&S Group

Departmental meetings including Management and laboratory staff meetings
### Table 1.4

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Frequency</th>
<th>Attendees</th>
<th>Aims</th>
<th>Minutes recording</th>
</tr>
</thead>
<tbody>
<tr>
<td>POCT Trust Working Group and subgroups</td>
<td>Meets up to 4 times a year</td>
<td>Consultant Biochemist (Chair) Chief and Senior BMS from Clinical Chemistry &amp; Haematology. Representatives from Infection Control and Risk &amp; Safety Managers Clinicians (including nurses) including Diabetic Education, Intensive treatment unit, Neonatal department and also Primary Care Trust and the Community.</td>
<td>To discuss POCT within the Trust</td>
<td>CHEMISTRY:Meetings/Chemistry POCT meetings</td>
</tr>
<tr>
<td>Laboratory Management Team meeting</td>
<td>Monthly</td>
<td>HOD, Clinical Scientists, Laboratory Lead, Section seniors, QL, Joint Reception Manager</td>
<td>To discuss strategy, quality issues and objectives, Operational overview of department.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Laboratory Operations meeting</td>
<td>Monthly</td>
<td>Laboratory Lead, Section seniors, QL, Joint Reception Manager, Senior MLA</td>
<td>To discuss and resolve Laboratory issues Review ISO progress</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Clinical Chemistry Quality and Improvement Meeting</td>
<td>Monthly</td>
<td>Consultant Clinical Scientist, Laboratory Lead, Senior staff, Pathology Quality and Improvement Manager, QL, Joint reception manager and if possible MLA/BMS</td>
<td>Monitor quality in all departmental sections. Improvements and ISO requirements</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Clinical Chemistry/Joint Reception Laboratory Meeting</td>
<td>Minimum one per month</td>
<td>All Staff</td>
<td>Actions arising and divisional information</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Clinical Chemistry Clinical Approval (CAP) meetings</td>
<td>Monthly</td>
<td>HOD, Consultant Clinical Scientist, Principal Clinical Scientists</td>
<td>To discuss clinical approval issues, new guidelines, departmental clinical discussions</td>
<td>CHEMISTRY:Meetings/Chemistry CAP meetings</td>
</tr>
<tr>
<td>POCT</td>
<td>Monthly</td>
<td>Consultant Clinical Scientist, Laboratory Lead, POCT manager, Pathology Quality and Improvement Manager, BMS 6</td>
<td></td>
<td>CHEMISTRY:Meetings/Chemistry POCT meetings</td>
</tr>
<tr>
<td>Team Huddles</td>
<td>Daily</td>
<td>Staff grades</td>
<td>Day to day running issues, Quality, H&amp;S</td>
<td>CHEMISTRY:Meetings/Chemistry/Huddles, paper copies in auto support</td>
</tr>
</tbody>
</table>
### Table 1.5
Clinical Microbiology

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Frequency</th>
<th>Attendees</th>
<th>Aims</th>
<th>Minutes record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Management Team (LMT) meeting</td>
<td>Weekly</td>
<td>HOD, Consultant Microbiologists, Lead BMS, Senior BMSs, QL, Laboratory Administrator</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of department.</td>
<td>Cmb_histo_bio on ‘histo_bio’/Minutes of Meetings/Lab Management Team</td>
</tr>
<tr>
<td>LMT meeting debrief</td>
<td>Weekly</td>
<td>Duty Senior BMS All non-clerical staff</td>
<td>To debrief LMT minutes and discuss any arising issues</td>
<td>Cmb_histo_bio on ‘histo_bio’/Minutes of Meetings/Lab Management Team</td>
</tr>
<tr>
<td>CPD meeting</td>
<td>Monthly</td>
<td>Any relevant staff</td>
<td>CPD</td>
<td>No minutes taken only attendance recorded and PowerPoint presentations Cmb_histo_bio on ‘histo_bio’/Cornish Microbiological Society/CMS Presentations</td>
</tr>
<tr>
<td>All staff meeting</td>
<td>6 monthly</td>
<td>All staff</td>
<td>Relevant current issues</td>
<td>Q-Pulse CMB-GEN-MINS-XX</td>
</tr>
<tr>
<td>Team huddles</td>
<td>Daily</td>
<td>MLA</td>
<td>Discuss daily lab issues</td>
<td></td>
</tr>
</tbody>
</table>

### Table 1.6
Diagnostic and Molecular Pathology

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Frequency</th>
<th>Attendees</th>
<th>Aims</th>
<th>Minutes recording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department Quality / Governance Group (DOG)</td>
<td>Monthly</td>
<td>Clinical Governance Lead, SD, Laboratory Lead, Chief BMSs, Section Leads, QL, Deputy QL, Clinical Audit Lead, POIM</td>
<td>Monitor quality in all departmental sections. Improvements and ISO requirements</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Senior team group</td>
<td>Bi-Monthly</td>
<td>SD, Laboratory Lead, Chief BMSs, Section Leads, POIM</td>
<td>To review EQA, new developments and DMP specific issues</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Cytopathology</td>
<td>Bi-Monthly</td>
<td>All Cytology staff</td>
<td>To discuss strategy, quality issues and objectives.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Human papillomavirus (HPV) Testing Group</td>
<td>Annually</td>
<td>Cytology and Microbiology senior BMS staff (including consultant BMS) and Lead consultants for each section</td>
<td>To discuss any HPV issues for either Cytology &amp;/or CMB</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Cytology Seniors Group</td>
<td>Weekly huddle</td>
<td>Cytology BMS staff</td>
<td>To review EQA, new developments and Cytology specific issues – Day to day running of the lab</td>
<td>S:RCH-HISTO/Cell Path meetings</td>
</tr>
<tr>
<td>Histology Laboratory Meeting</td>
<td>Bi-Monthly</td>
<td>SD, Laboratory Lead, POIM, All Histology staff</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of department.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Section</td>
<td>Frequency</td>
<td>Participants</td>
<td>Agenda</td>
<td>Notes</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------</td>
<td>----------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Molecular Cellular Biology Unit (MCBU)</td>
<td>Bi-Monthly</td>
<td>Consultants with specialist interest, SD, Laboratory Lead, Senior Histology staff</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of MCBU.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Research, Development and Innovation (Trials)</td>
<td>Based on trial release</td>
<td>SD, Laboratory Lead, Trials team, QL</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of Trial.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Consultants Meeting</td>
<td>Monthly</td>
<td>SD., Consultants, Laboratory Lead</td>
<td>To discuss strategy, quality issues and objectives. Operational overview which affect the consultants and DMP.</td>
<td>S:\RCH-HISTO\Cell Path meetings</td>
</tr>
<tr>
<td>Training Education Research and Audit (TERA)</td>
<td>Adhoc</td>
<td>Organised by Histology BMS, attended by all available DMP staff</td>
<td>Educational lunchtime meeting for all DMP staff</td>
<td>S:\RCH-HISTO\Cell Path TED\TERA</td>
</tr>
<tr>
<td>Office</td>
<td>Bi-Monthly</td>
<td>Laboratory Lead, Administration Manager, Secretaries and Administration staff</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of the DMP office.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Mortuary Services</td>
<td>Quarterly</td>
<td>Laboratory Lead, Mortuary Manager and Mortuary Technicians.</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of the mortuary.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Bereavement Meetings</td>
<td>Quarterly</td>
<td>Laboratory Lead, Mortuary Manager, Bereavement officers</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of Bereavement.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Huddles and Team Briefs</td>
<td>Daily</td>
<td>Staff teams and section leads</td>
<td>Day to day running issues, Quality, H&amp;S</td>
<td>S:\RCH-HISTO\Cell Path meetings\Histology daily team briefs Cytology Daily Diaries (LBC and Tower block labs)</td>
</tr>
<tr>
<td>Multi-Disciplinary Team (MDT) Meetings</td>
<td></td>
<td>Relevant MDT Team members including specially Consultant Pathologist representative from Pathology</td>
<td>List of patients discussed in the meeting and the outcomes of discussions are saved under each Consultant Pathologist in their specific folders on the server</td>
<td></td>
</tr>
</tbody>
</table>
DMP information communication pathway

- Directorate Management Meeting
- Specialty Meeting
  - DMP Seniors Meeting
  - DMP Consultants Meeting
- Directorate Governance meeting
  - DQG/Monthly QMS and clinical Governance template review
  - Section Meetings
    - Daily Huddles/Team Briefs
RCHT HTA Reporting Structure

Cathy Byrne
Chief Executive

Dr Bryson Pottinger
License Holder
CSCS Clinical Director

DI and LBMS DMP
Mr Peter Helliwell

Associate Director

Associate Director

TMC Trust Governance Committee

Directorate Governance Group

Directorate Governance Lead
Mrs Janet Gardner

Person Designate Mortuary Manager
Mr Kevin Hammett

Person Designate and Senior BMS DMP
Mrs Georgie Purvis Mr Matthew Coles

Person Designate Paediatric Staff Nurse Emergency Department
Melanie Griffiths

Person Designate Consultant Obstetrics and Gynaec
Rob Hopkins

Person Designate Consultant Paediatrician
Andrew Collinson

Accountability and Responsibility

Advisory Groups
Table 1.7

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Frequency</th>
<th>Attendees</th>
<th>Aims</th>
<th>Minutes recording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Management Team meeting</td>
<td>Monthly</td>
<td>HOD, Clinical Scientists, Laboratory Lead, Section seniors, QL, PQIM</td>
<td>To discuss strategy, quality issues and objectives. Operational overview of department.</td>
<td>G:\Personnel - B\MEETINGS\SENLAB</td>
</tr>
<tr>
<td>Haematology/Blood Transfusion Laboratory Meeting</td>
<td>Fortnightly</td>
<td>All Staff</td>
<td>Actions arising and divisional information</td>
<td>G:\Personnel - B\MEETINGS\LAB MEETINGS</td>
</tr>
<tr>
<td>Transfusion Management Meetings</td>
<td>Daily</td>
<td>Blood transfusion senior staff</td>
<td>Blood transfusion issues</td>
<td>G:\Blood Transfusion\TMG meetings</td>
</tr>
<tr>
<td>Hospital Transfusion Team (HTT)</td>
<td>Monthly</td>
<td>Laboratory Lead, Clinical consultant, transplant Practitioner, consultant anaesthetist</td>
<td>Blood transfusion issues</td>
<td>G:\Blood Transfusion\HTT</td>
</tr>
<tr>
<td>Hospital Transfusion Committee (HTC)</td>
<td>3 times a year</td>
<td>3 x medical representative from all specialties</td>
<td>Blood transfusion issues</td>
<td>G:\Blood Transfusion\HTC</td>
</tr>
<tr>
<td>MLA meetings</td>
<td>Monthly</td>
<td>All lab MLA’s</td>
<td>Lab issues</td>
<td>B\MEETINGS\MLA MEETINGS</td>
</tr>
</tbody>
</table>

5.11 Quality and Improvement Manager (ISO Clause 4.1.2.7)

The PQIM is accountable to the PSM and the job description is available on Q-Pulse.

Together they oversee the Pathology QMS, facilitate compliance with regulatory authorities and ensure that the QMS functions efficiently and effectively with the use of Q-Pulse.

The PQIM liaises with the directorate quality and governance lead and attends the monthly directorate governance meeting and H&S meeting escalating any quality or H&S issues within Pathology.

The PQIM is informed of changes in the service requirements via attendance at regional quality managers meeting, networking with other Pathology quality managers, changes to RCPPath and other guidance documents, attendance at Trust H&S, quality and governance meetings.

The majority of the Pathology wide documents are written by the PQIM, reviewed by the departmental QL’s and then approved by the Pathology Management within the specialty meeting which is held monthly. The exceptions to this are the quality manual which is written by the PQIM and reviewed and approved by the Pathology Management and the IT documents which are written by the Pathology IM&T Manager and then approved by the Pathology management.

Each laboratory and section lead across Pathology is responsible for the maintenance of the QMS in their area.

The QL for each laboratory reports monthly to the PQIM at the PQG regarding quality issues, EQA issues and incidents.
5.12 Quality Management System (ISO Clause 4.2, 4.2.1, 4.2.2 & 4.2.2.1)

The Pathology directorate ensures that the QMS is integrated into all roles within Pathology and ensures that it is at the centre of all procedures and processes carried out within Pathology.

Senior BMS's, QL's and section leads produce monthly QMS template reviews (apart from CMB). These are presented at the monthly departmental quality meetings, senior staff meetings or PQG.

The monthly template review reports are designed to capture information to support compliance with regulatory authorities and to provide a framework to sustain total quality management.

On review of the templates, actions are set and captured in Q-Pulse. Anything that requires escalation is reported on the monthly Pathology priority report produced by the QL and presented at the PQG. Any issues are then escalated to the directorate via the PQIM if required.

The principles of the QMS are communicated to staff by various ways, including Departmental Induction Manual, QMS training and QMS competency for all staff.

[Refer to SOP PA-GEN-SOP-16, PA-TRAIN-MAN-7 and document template PA-GEN-FORM-18]
5.13 Quality Manual (ISO Clause 4.2.2.2)

The Quality Manual (QM) has two main functions and they include providing an overview of the QMS implemented by the Pathology services and to it also provides information for service users including accreditation bodies e.g. UKAS, MHRA etc.

To facilitate and maintain the QMS across all departments, Pathology wide policies and procedures describe the generic principles to be applied by each department. These documents are managed by the PQIM and approved in the specialty management meeting.

These documents include -

- Change Control [PA-GEN-SOP-10]
- Control of clinical material [PA-GEN-SOP-12]
- Control of process and quality records [PA-GEN-SOP-14]
- Internal Audit SOP [PA-QMS-SOP-2]
- Internal Quality Control [PA-GEN-SOP-2]
- Laboratory Health and Safety Manual [PA-HS-MAN-1]
- Management of Internal and External Complaints and User feedback Within Pathology [PA-QMS-SOP-4]
- Management of materials [PA-GEN-SOP-25]
- Pathology Laboratory information management system (LIMS) [PA-GEN-SOP-8]
- Personnel management [PA-GEN-SOP-22]
- Preparation and control of documents [PA-GEN-SOP-16]
- Principles of External Quality Assurance [PA-GEN-SOP-32]
- Principles of service level agreements [PA-GEN-SOP-34]
- Procurement and management of equipment [PA-GEN-SOP-24]
- Recording and managing nonconformities and incidents [PA-QMS-SOP-3]
- Referrals to and from external laboratories [PA-GEN-SOP-26]
- Reports, amended reports, clinical advice and interpretation [PA-Gen-SOP-21]
- Sample transport requirements and guidelines [PA-GEN-SOP-27]
- Specimen acceptance policy [PA-GEN-POL-1]
- Training Policy [PA-TRAIN-POL-3]
- Trust Procedures and Policies
- Trust Risk Management Strategy & Policy
- Trust Health & Safety Policy
- User guide [PA-GEN-MAN-2]

Specific and detailed information and documentation is available within each department.

The quality manual is reviewed bi-annually or following an adverse event, internally or externally sourced audit which suggests that deficiencies exist or improvements could be made. It is circulated to all laboratory staff via Q-Pulse – staff are required to read the contents and acknowledge using Q-Pulse.
5.14 Document control (ISO Clause 4.3)

There is a pan-Pathology procedure named Preparation and Control of Documents [PA-GEN-SOP-16] which outlines the procedure for preparation, review and maintenance of the all documents within Pathology.

The documents are managed through Q-Pulse. All the documents are held electronically and any hard copies are only printed out if required e.g. contingency procedures and technical procedures. Any printed copies are recorded in the document record on Q-Pulse in case of the requirement to change it for a new version.

All staff within Pathology have a user name and password to enable log in to Q-Pulse. This program is on all computers within Pathology and when a document has been read by the staff member an electronic acknowledgement is required.

Audits are conducted within each department to monitor compliance. Document control workloads are monitored and actions generated using the monthly QMS template.

5.15 SLA (ISO Clause 4.4, 4.4.1 & 4.4.2)

The procedure for the selection and purchasing of external services and establishing SLA’s is documented in:

- Principles of Service Level Agreements (SLA) in Pathology [PA-GEN-SOP-34]
- RCHT SLA template – Trust as the commissioner [PA-GEN-EX-16]
- RCHT SLA template – Trust as the provider [PA-GEN-EX-17]
- RCHT SLA template – (2 way) [PA-GEN-EX-18]

RCHT does not require SLA’s between service users within RCHT.

SLA’s with user’s external to RCHT are supported, reviewed and managed via RCHT, with direct Pathology input and review.

5.16 Examination by Referral laboratories (ISO Clause 4.5 & 4.5.1)

The general requirements/principles for specimen referral to reference laboratories are described in the Specimen Referrals to and from External Laboratories SOP [PA-GEN-SOP-26]. Each laboratory has its own specific criteria for the choosing of the relevant referral laboratory and these can be found on Q-Pulse within the departmental procedures.

The accreditation status of the referral lab / centre should be checked every two years and recorded for each department.

5.17 External services and supplies (ISO Clause 4.6)

Arrangements for procurement and management of external supplies and services including reagents, consumables and equipment are included in -

- Procurement and management of equipment [PA-GEN-SOP-24]
- Change control using Q-Pulse CA/PA module [PA-GEN-SOP-36]
• Change control procedure [PA-GEN-SOP-10]

A list of approved suppliers of equipment, reagents and consumables is kept within the Trust Electronic Requesting Ordering Service (EROS) system.

Each department ensures that the supplies procured are appropriate to the needs of the service user.

The performance of these suppliers is monitored annually, or on completion of contract period, or if there is an adverse incident / issue. These incidents are recorded using the incident reporting module in Q-Pulse.

5.18 Advisory Services (ISO Clause 4.7)

The Pathology User Guide [PA-GEN-MAN-2] allows communication from Pathology to our service users and this document can be found on Q-Pulse and the RCHT intranet

http://www.rcht.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/Pathology/PathologyHandbook.pdf

This information includes:
• Tests offered by Pathology
• Advice on choice of examination
• Use of services within Pathology
• Type of specimen needed for tests
• Limitations of examinations
• Frequency of requested examination
• General advice on specimen collection and transport
• Contact details for technical and clinical advice

Interpretative reports and clinical advice are the responsibility of the Pathologists, Clinical Scientists and competent BMS. Such staff are always available to discuss results with clinical colleagues. Advice on individual clinical cases or in terms of obtaining professional judgement on specific results can be obtained by contacting the specific laboratory.

Contact numbers are as follows:

• Blood Transfusion - 01872 25 3856
• Clinical Chemistry - 01872 25 2540/2548
• CMB - 01872 25 4900
• DMP - 01872 25 2550
• Haematology - 01872 25 2502

Clinical staff are also available to assist users to obtain the most effective utilisation of the laboratory service. Laboratory staff are also able to offer advice to assist with the correction of specific problems that may be experienced by users, such as instances of specimen rejection due to a failure to meet laboratory acceptance criteria.
5.19 Resolution of Complaints (ISO Clause 4.8)

This process is explained in the Management of Internal and External Complaints and User feedback Within Pathology SOP [PA-QMS-SOP-4].

The laboratories aim to provide a high quality and responsive service appropriate to users’ and patients’ needs. The laboratories enjoy good relations with users and receive few complaints. Departments attach a high priority to the resolution of complaints, whether this involves assistance with queries referred from the RCHT complaints department or dealing with complaints from users (staff).

Formal complaints are currently managed externally to Q-Pulse. Further development of Q-Pulse will enable future complaints to be captured and managed through the Q-Pulse Corrective Action/Preventative Action (CA/PA) module.

Information regarding formal complaints is sent from the Trust complaints team and assigned to a trained investigating office. Investigations and action / resolutions plans are completed within set time frames and returned to the complaints team.

All formal complaints are reviewed at the monthly QMS template review within each section and also at directorate governance meeting.

5.20 Identification and control of non-conformities (ISO Clause 4.9)

To improve the quality of our procedures and processes all errors or non-conformities are investigated and corrective actions are taken.

The principles designed to effectively manage nonconforming examinations or activities are described in:

- Recording and managing nonconformities and incidents [PA-QMS-SOP-3]
- Q-Pulse intermediate and Power user training manual – Incident reporting and investigation [PA-TRAIN-MAN-3]
- Blood transfusion training manual – Incident reporting and investigation [PA-TRAIN-MAN-6]

Specific Departmental laboratory Instructions are available locally.

Any non-conformity that has been raised from audits, staff actions, meetings or errors in the department is recorded onto Q-Pulse within the CA/PA module or incident reporting modules. Capturing this information supports improvements to service delivery by increasing efficiencies and to provide quality assurance to all stakeholders by ensuring the expectations of the service users are met.

Incidents are reported by all grades of staff on Q-Pulse. The seniors in each section are responsible for reviewing incidents and carrying out initial actions as they are raised. They assess the severity and impact of the incident and close it as an occurrence or conduct a full investigation. All incidents with an investigation are risk assessed, categorised, severity assessed and the root cause conducted where required. All investigations are approved and closed by the line manager of the investigator.
It is documented where incidents are further reported onto the trust incident reporting software Datix in accordance with the agreement with the Trust risk committee e.g. if the risk on Q-Pulse is moderate or above or if the incident is an H&S incident. Refer to [PA-TRAIN-MAN-3]. The Trust risk department have access to Q-Pulse.

Incidents with a severity of moderate and above are recorded on the priority template and presented by each QL at the monthly PQG.

Trends on the Datix and Q-Pulse are carried out quarterly and communicated at directorate meetings including the H&S meeting, PQG and Pathology Directorate meeting.

All incidents on Datix are handled by the PQIM who nominates an investigator to carry out the investigation and obtain root causes and preventative actions. The PQIM will close the Datix incident if the investigation has been completed satisfactorily.

### 5.21 Corrective action and preventative action (ISO Clause 4.10 & 4.11)

The principles regarding corrective actions for Pathology are covered in the following documents -

- Recording and managing nonconformities and incidents [PA-QMS-SOP-3]
- Q-Pulse intermediate and Power user training manual – Incident reporting and investigation [PA-TRAIN-MAN-3]
- Blood transfusion training manual – Incident reporting and investigation [PA-TRAIN-MAN-6]
- Q-Pulse intermediate and Power user manual – CA/PA and Suggestions [PA-TRAIN-MAN-5]
- Q-Pulse CAPA / Action completion guidance [DMP-GEN-LI-12]

Types of CA/PA’s include:

- Meeting actions
- Individual Staff actions
- Performance Development Review (Appraisal) actions
- Equipment error logs and issues requiring investigation / engineer support
- Change control
- Improvement suggestions – Can be via Q-Pulse or anonymously in suggestion boxes/book.
- Inductions (Permanent and Temporary). Refer to [PA-TRAIN-MAN-13] All staff attend a Corporate induction described in the RCHT Induction Policy (available from the Human Resources Department) on the first 2 days of employment. Departmental orientation and induction is conducted and records are kept which are completed jointly by inductor and inductee and kept in the employee’s personal file. A comprehensive RCHT staff handbook is available to staff on the intranet.
  - Staff Leavers [PA-TRAIN-MAN-14]
  - Staff commendations

All departments co-ordinate their own actions from CA/PA’s and these are monitored at the PQG, DQG or management meetings using the quality template. The actions are recorded and managed within Q-Pulse (Each action should incorporate a root cause trending for proactive quality management and auditing purposes which is carried out quarterly).
Performance on completion and the quality of completion of CA/PAs is monitored across Pathology on a monthly basis.

5.22 Continual Improvement (ISO Clause 4.12)

The Pathology specialty is committed to meeting the needs of our users and therefore uses a total QMS which incorporates continuous quality improvement in all areas of the service.

Areas for improvement are identified by:
- The monthly quality template and priority reporting template
- Risk management
- Service user and staff suggestions
- Incidents
- Error logs
- CA/PA’s
- Review of progress with objectives
- Quality management meetings
- Audit

For simple improvements, actions are raised in Q-Pulse. More complex issues may require an investigation, root cause analysis (RCA), risk assessment, an action plan and business case. These are fed back to staff via staff meetings and team huddles.

5.23 Control of records (ISO Clause 4.13)

The principles of control of records are described in Control of Process and Quality Records [PA-GEN-SOP-14].

Each department is responsible for its own data and information. Records are retained for at least the minimum periods specified by the laboratory and with the national guidance document ‘The retention and storage of pathological records and specimens’ as co-authored by the Royal College of Pathologists (RCPath) and the IBMS.

All documentation is kept confidential, secure in an optimal storage environment to prevent deterioration and unauthorised access. Storage and release of documents is controlled and recorded. Each department is responsible for the retention and storage of their own records detailed instructions, retention times and SOPs are available on Q-Pulse for each section.

5.24 Evaluation, risk and audits (ISO Clause 4.14)

The principles of evaluation and audit are covered in pan-Pathology documents:

- Internal quality auditing guidelines [PA-QMS-GUIDE-3]
- Q-Pulse Training Manual - Audit Module [PA-TRAIN-MAN-8]
- Laboratory internal audit [PA-QMS-SOP-2]

These documents cover key areas including:
- Periodic review of requests and suitability of procedures and sample requirements
- Assessment of user feedback
- Staff suggestions
- Internal audit
- Risk management
- Quality indicators
- Review by external organisations

The PQIM defines and implements the programme of internal audits for Pathology and this will then be agreed in the AMR by Pathology specialty management.

In the transition to ISO 15189:2012 compliance, the pan-Pathology audit schedule structure will focus on 5 clauses each year on a rolling programme. The priority clauses for audit are identified by the ISO gap review conducted by each department. Details are recorded within the audit module in Q-Pulse.

The results from each Pan-Pathology audit are written up as a report and sent to all Pathology management and QL’s. The findings are then discussed at Pathology directorate meeting and any actions agreed.

Only competent staff or staff undergoing audit training may conduct audits and this is currently monitored within each department. Audit actions are allocated to specific individuals for completion within a set time frame. The audit findings and actions performed in each department are reviewed by a senior member of staff or specialist clinical lead. On completion of the audit actions, the audit is reviewed and closed by the section line manager / clinical audit lead.

Clinical and laboratory audit schedules are constructed at departmental AMRs in accordance with trust priorities, standards set by regulatory bodies and review of pre examination, examination, post examination processes and QMS to ensure continual improvement and to ensure the suitability of requests, procedures and sample requirements.

Each department has clinical auditor and the clinical audits are registered with the trust audit team.

The results of internal audit are captured on the monthly quality template and reviewed and actions discussed at quality / management meetings.

A Pathology user survey is sent our annually to all Pathology service users and this is treated as an audit. Once the results have been collected and analysed, a written report is distributed to all service users which contains the results from the survey and the actions for improvement raised and the action plan documented.

Risk Assessments are recorded in Q-Pulse (DMP – audit module all other departments use the document module). Risk assessments are reviewed annually (CMB review biennially) or where there has been a significant change to a process, to the environment or prompted following an incident or where a hazard has been identified. Risk assessments are conducted by individuals that have undergone risk assessment training.

Risks that require escalation are placed on the RCHT Datix risk register and captured on the quality template and reviewed at quality and management meetings and are escalated to directorate if required.
Any changes in these risks are ratified at the Pathology specialty meeting before being communicated to directorate.

5.25 Staff suggestions (ISO Clause 4.14.4)

Staff suggestions are raised in a variety of ways to allow staff to make suggestion via various mechanisms. These include-

- Staff meetings
- Team meetings
- Q-Pulse – using the CA/PA module
- Staff suggestion boxes/book – allow anonymous suggestions
- Discussions with senior staff
- Email
- Appraisals

All suggestions are discussed at senior level meetings and then fed back to the staff via Q-Pulse, laboratory meetings, huddles or discussion with the staff member who made the suggestion.

5.26 Management review (ISO Clause 4.15)

Approach to the Pathology AMR

The Pathology AMR is conducted every 12 months and takes place after the departmental AMRs. The information, minutes and actions plans are captured within the Q-Pulse incidents
and eforms module and feedback is communicated to staff via staff meetings. The objectives are written for the forthcoming year and are reviewed each quarter by each department and stored in the Q-Pulse audit module. The Pan-Pathology objectives are discussed in the PQG and then agreed within the Pathology specialty meeting. These are available on Q-Pulse in the audit module.

5.26 Personnel (ISO Clause 5.1)

The specialty personnel procedures are governed by the RCHT policies and procedures which can be found on the intranet.

The principles in personnel management within Pathology are described in:

- Personnel Management [PA-GEN-SOP-22]
- Pathology Directorate Training Policy [PA-TRAIN-POL-3]

These documents cover key areas such as:

- Personnel qualifications
- Job descriptions
- Induction
- Training
- Competency
- Review of staff performance
- Continuing education and professional development
- Personnel records

Laboratory Leads assess adequacy of numbers in consultation with the PSM and SD taking into account staffing models and guidance issued by the Royal College of Pathologists (RCPath). Staffing levels are monitored against compliance with turnaround times and key performance indicators.

Staff records are maintained according to Records Management: NHS Code of Practice (2009). General Staff details are recorded on Q-Pulse this information includes: Name, email, Job role, and Escalation manager.

Each individual department maintains their own staff information and this includes personnel qualifications, job descriptions, training, experience, professional registration details and personal information.

Staffing changes and updates and progress with training plans and competency assessments are reviewed and reported in departmental meetings.

It is mandatory for all new staff to attend the RCHT induction and then complete the departmental induction prior to starting their new role within Pathology. The records for both inductions are held by the department in the staff members personnel file (P: file) and the Trust induction records are also held by Learning and development department within the Trust and via ESR.
The departmental induction programmes are available on Q-Pulse.

The RCHT induction covers –

- Counter Fraud
- Dementia awareness
- H&S
- Independent Listening
- Manual Handling (non-patient)
- Medical gases awareness
- Radiation protection awareness
- Stress management
- Safeguarding adults
- Waste management

All personnel are required to undertake mandatory training provided by the trust. The timeframe for repeating mandatory training is specific to the training event and is determined by the trust. Records for training are held by the trust.

Each department has a named member of staff who is responsible for training and they roll out the training to the required staff. All staff members are assigned a supervisor and the training undertaken must be supervised and signed as competent before they are deemed competent in the task. All staff are required to maintain their competencies specific to their job role and these competencies are specific to each department and can be found on Q-Pulse.

All training and development records can be found in the p: file of the staff member and are discussed at the staff members annual Personal Development Review (PDR). The professional registration is checked bi-annually and this is also kept in the P: file.

The PDR is carried out annually for each staff member and this will include discussion on the following -

- Job description
- Personal objectives
- Training needs
- Evidence of individual actions that haven't been actioned
- Issues that need to be discussed
- Agreed development plans
- CPD

All personnel that carry out the PDR process (e.g. Laboratory Leads and senior staff) have received appropriate training from the Trust.

The records of these PDR are kept within the staff members P: file.

All staff participate in CPD (There is currently a voluntary scheme provided by IBMS which most BMS participate in). The staff keep their own records of CPD e.g. task learning outcomes, training and lunchtime lectures and is used to demonstrate that they are fit to continue their duties.
5.27 Accommodation and environmental conditions (ISO CLAUSE 5.2)

Annual audits are conducted to assess and monitor the suitability of the accommodation and environment conditions throughout the departments within Pathology. These audits include:

- H&S
- Fire
- Environment and facilities against regulatory standards
- Anti-terrorism

Audits are stored on Q-Pulse.

Risk assessments are conducted and reviewed annually, in the event of a significant change to process / environment / facilities or prompted following an incident or identification of a hazard. Risk assessments are conducted by competent staff and are available on Q-Pulse.

If facilities / environment are deemed not suitable risks are managed locally and documented on the Datix risk register. If issues cannot be addressed locally then they are escalated to divisional and the trust risk committee.

Current future laboratory provisions planning under review for completion of a managed laboratory service contract.

General maintenance of Pathology is performed by the Trust Estates department. Housekeeping tasks e.g. vacuuming, mopping and changing the bins is managed by an external company.

Laboratory and office facilities

Each laboratory lead is responsible for maintaining:

- Safe working environment for staff and visitors – this includes sites for primary sample collection
- Working environment and facilities do not adversely affect sample integrity or quality of examinations
- Security – controlled and restricted access where required
- Ensuring compatible activities are carried out in specific areas within regulatory guidelines and health and safety law.
- Regular environmental monitoring where required

All staff are responsible for keeping areas clean and tidy – This is covered in staff induction and training protocols and within the Trust SLA with MITIE.

Storage facilities

Each laboratory lead is responsible for storage facilities and considers the following:

- Sufficient space
- Preservation and integrity of materials is maintained
- Secure – no unauthorised access
• Prevention of cross contamination
• Safe storage (Hazardous material and reagents)
• Safe disposal facilities
• Compliance with regulatory and legal bodies

Process and quality records – physical capacity is limited in most departments at present, but electronic archiving is considered where long term storage is required.

Clinical materials – capacity is limited in most departments for archived material; some (e.g. DMP and Haematology) have secured off-site arrangements.

**Staff facilities**

The PSM is responsible for the provision of:

• Sufficient washroom facilities
• Drinking water
• Storage for Personal Protective Equipment (PPE)
• Secure storage for personal items (Coats, bags)

**Patient sample collection facilities**

Pathology provides the following facilities for its patients if required –

• Patient and accompanying person comfort – disabled access, toilets
• Sample collection can be conducted without invalidating results or adversely affecting the sample quality
• First aid is available

**5.28 Laboratory equipment, reagents and consumables (ISO CLAUSE 5.3)**

The information describing the principles applied to the management of equipment and reagents is included in the following documents:

• Procurement and management of equipment [PA-GEN-SOP-24]
• Management of material (Reagents, calibration and quality control) [PA-GEN-SOP-25]

These documents cover key areas such as:

• Acceptance testing
• Instructions for use
• Calibration and metrological traceability
• Maintenance and repair
• Adverse incident reporting
• Records
• Reception and storage (Reagents and consumables)
• Inventory management (Reagents and consumables)
The criteria for the acceptance testing for all reagents and consumables can be found in departmental SOP’s.

All equipment involved in examination procedures are recorded on and managed using Q-Pulse by each department.

All equipment issues are captured on Q-Pulse using the CA/PA module or equipment module and reviewed using the quality template.

The PQIM is responsible for organising with external companies the calibration and preventative maintenance of all pan-pathology equipment e.g. pipettes, balances and centrifuges.

The section leads are responsible to ensure the departmental equipment is maintained, calibrated and fit for use and ensures that any decontamination prior to external work is carried out. Following any equipment errors and ‘down’ periods the section lead must also ensure that an appropriate validation has been carried out before the equipment can be put back into use. Change control for all newly acquired equipment is captured on Q-Pulse.

Laboratories currently have sufficient and appropriate equipment to meet the requirements of the service. Forward replacement plans are updated annually as part of the RCHT major capital equipment programme.

The management and acceptance testing of all reagents and consumables is managed within each department and the procedures for this process can be found on Q-Pulse.

5.29 Pre-examination processes (ISO Clause 5.4)

Information for patients and users

Pathology has information available to patients and users in the Pathology user guide [PA-GEN-MAN-2] and Specimen acceptance policy [PA-GEN-POL-1] which are available on the RCHT website.

Request Forms

All request forms in Pathology are formatted to be compliant with ISO 15189 clause and discipline specific regulatory requirements.

Electronic ordering (order comms) has been in use at RCHT over a period of 2 years. GP electronic requesting is in the process of being rolled out.

The laboratory ensures the proper completion of request forms as per Specimen acceptance policy [PA-GEN-POL-1].

Primary sample collection and handling and Pre collection and collection activities

Information is provided in Pathology user guide [PA-GEN-MAN-2] which is available on the RCHT Intranet.
For all cancer screening programme samples all staff involved with the sample pathway must sign the NHS cervical screening programme (NHSCSP) confidentiality declaration annually [DMP-GEN-POL-2]. Section 251 prevents the need for consent to use patient information for national statistics and audit.

**Sample transportation**

Specimen transport within the RCH is via staff, hospital porters or Pneumatic air tubes system. The porters have dedicated pick up and drop off times during working hours Monday to Friday and then samples are picked up on an emergency basis out of hours. The Pneumatic tubes are in use 24 hours a day and are maintained by the RCHT estates department.

Any samples coming from off-site users e.g. GP’s and community hospitals are transported via Hospital couriers or freewheelers. The couriers have dedicated pick up and drop off times during working hours Monday to Friday and any out of hours pick up is carried out by the freewheelers.

Information is provided in:

- Pathology user guide [PA-GEN-MAN-2]
- Pathology sample transport requirements and guidelines [PA-GEN-SOP-27]

Each department have detailed documentation for these processes.

**Sample reception**

There are documented procedures within each department for specimen reception and are available on Q-Pulse. These cover key items such as:

- Specimen traceability and labelling
- Acceptance criteria assessed by authorised, competent personnel
- Issues that would affect the quality of the examination result / sample integrity are recorded – consideration of the effect on the report
- Identification of urgent / priority samples

**Pre-examination handling, preparation and storage**

The principles of handling and storage of specimens are described in Control of clinical material [PA-GEN-SOP-12] in accordance with recommendations from the Royal College of Pathologists (Retention and storage of pathological records and specimens 5th edition), HTA and ISO 15189:2012.

Departmental documented procedures aim to ensure the appropriate identification, indexing, confidentiality, security, storage and release of materials and records.

These departmental documents for retention of clinical materials include:-

- Blood transfusion: BT-LI-55
- Chemistry - Auto: CH-AUTO-LI-12
- Chemistry - Manual: CH-MAN-LI-1
5.30 Examination processes (ISO Clause 5.5)

Procedures are available for all examination processes within Pathology. All documentation is stored and controlled in Q-Pulse. Hard copies of control documents are available where required – for example laboratory instructions located at the site of use or contingency / emergency procedures.

Staff are competency assessed and examination audits are conducted to ensure staff follow standardised procedures.

Selection, verification and validation of examination procedures

Currently there are 2 change control processes which have been implemented by the Pathology service. One is for Blood transfusion to ensure compliance with MHRA and the other is for the rest of Pathology to use.

The change control is to ensure that all new or modified examination procedures have been validated and / or verified before being put into routine use. When analytical procedures are changed with the effect that results, and/or their interpretation are significantly different or there is a comparison of a test with a new test, the implications are explained and communicated to staff and service users before the change is implemented.

The principles of change control are described in the following documents:

- Change control [PA-GEN-SOP-10]
- Change control using Q-Pulse CAPA module [PA-GEN-SOP-36]

Change control processes are captured on the quality template and progress is reviewed monthly.
Validated supplier protocols are referenced in SOPs.

Historical procedures implemented prior to ISO accreditation have undergone external and internal quality assurance and retrospective validation. Issues associated with these procedures will be highlighted and addressed by a total QMS.

**Measurement Uncertainty**

There is a pathology document describing the overarching principles of Measurement Uncertainty (MU) [PA-GEN-SOP-33].

Each department is responsible for documenting MU for quantifiable examinations that have critical quantitative values.

The MU are available to any service user upon request.

**Biological reference intervals or clinical decision values**

These biological reference ranges and critical values are available on request or they can be found in the Pathology user guide [PA-GEN-MAN-2].

**5.31 Ensuring the quality of examination results (ISO Clause 5.6)**

The Pathology service strives to ensure the quality of examinations by performing them under controlled conditions and checking that the intended analytical specifications and results are achieved.

These conditions include:

- Implementation of appropriate pre examination processes
- The provision of trained and competent staff, appropriate premises and environmental conditions, equipment and materials, information systems, and the use of documented procedures
- Quality ethos
- Good laboratory ethics
- The use of internal quality control (IQC) – records of dates, source and expected results of IQC material
- Verification of IQC material prior to routine use
- The determination of uncertainty (where relevant and possible)
- Calibration of measuring systems
- Verifying the comparability of results
- Participating in EQA schemes
- Audit

These principles are described in the following documents:

- Internal quality control in Pathology [PA-GEN-SOP-2]
- Internal quality auditing guidelines [PA-QMS-GUIDE-3]
- Principles of External Quality Assurance [PA-GEN-SOP-32]

Protocol specific documents for each department are available on Q-Pulse.
Daily IQC errors are logged locally, whilst any poor performance or IQC failure is captured on Q Pulse. Persistent poor performances are reported to the lab leads and then reported on the Pathology quality priority reporting template and presented at the PQG where actions plans are discussed. Issues are escalated to divisional governance group by agreement with the LBMS which is discussed at specialty meetings if required.

Patient results are not released until IQC passes are obtained or risk management plans are documented and in place.

**Interlaboratory comparisons**

The following document Principles of EQA [PA-GEN-SOP-32], describes the approach to interlaboratory comparisons for Pathology. Each laboratory has specific documents that detail the participation in schemes and alternative assurance where schemes are not available or not participated in.

- Blood Transfusion: BT-SOP-47
- Clinical Chemistry: CH-QUAL-LI-5
- CMB: CMB-GEN-SOP-11
- DMP: DMP-HI-SOP-18
  - DMP-IMM-SOP-7
- Haematology: HA-AH-SOP-26

Records are kept and are readily available for examination. The EQA specimens are processed in the same way as patient specimens.

The results of EQA schemes are published within the relevant area and communicated to staff via staff meetings and notice boards. EQA for each department is reviewed using the quality template on a monthly basis at the PQG.

EQA poor performance is captured on Q-Pulse and subsequently on the monthly quality template and presented at the PQG where actions plans are discussed. Issues are escalated to specialty meeting and then to divisional governance group by agreement with the laboratory managers.

**5.32 Post-examination processes (ISO Clause 5.7)**

**Review of results**

The review of results from the examinations are undertaken and authorised by competent staff e.g. BMS, clinical scientist or Consultant, who ensure the correct result is being released for the correct patient.

**5.33 Reporting of and release of results (ISO Clause 5.8 and 5.9)**

The report, amended reports, clinical advice and interpretation SOP [PA-GEN-SOP-21] describes the processes to be adopted by each department.

Detailed procedures are available for each section.
5.34 Laboratory information management (ISO Clause 5.10)

The principles of the Laboratory Information Management System (LIMS) (Winpath) are described in the following document:

- Winpath business continuity SOP [PA-GEN-SOP-19]

Department specific documents are available on Q-Pulse.

Pathology has a documented procedure to ensure the day to day running of LIMS and confidentiality of patient information is maintained at all times. There are contingency plans documented in the case of IM&T failure and the system is backed up daily by Cornwall Information Technology Services (CITS) to safeguard against tampering or loss.

To ensure verification of the system and the accuracy of results regular audits are run by the Pathology IM&T manager to ensure this verification of results.

Authorities and responsibilities

The Pathology IM&T Manager manages the LIMS alongside the Pathology IT team.

Personnel within Pathology have unique usernames and passwords to allow them access to LIMS and patient information. These usernames allow the authorised access to certain areas within LIMS according to their roles and responsibilities.

All activity within the LIMS can be subject to audit.

All staff are trained in laboratory ethics and data protection at induction and through departmental QMS training. Any breach of confidentiality is taken very seriously and fully investigated.

Electronic patient information stored outside the LIMS must be registered in accordance with the Caldicott principles.

Information system management

Changes to the LIMS are subject to Q-Pulse change control, testing and validation prior to implementation. Support from the supplier and RCHT IM&T department is used where required. This is co-ordinated by the IM&T manager with support of the laboratory managers and IT leads.
APPENDIX 1 – TRUST BOARD, DIRECTORATE, SPECIALTY AND DEPARTMENTAL STRUCTURES

Royal Cornwall Hospital Trust Board

- Kathy Byrne
  Chief Executive

- Dr Jon Andrewes
  Chairman

- Vacant
  Company secretary

- Paul Bostock
  Chief Operating Officer

- Christine Perry
  Interim Nurse Executive

- Karl Simkins
  Director of Finance & Performance

- Susan Young
  Interim Director of HR

- Dr Rob Parry
  Medical Director

- Ethna McCarthy
  Director of Strategy & Business Development

- Non-Executive Directors
  Roger Gazzard (vice chair)
  Dr Mairi McLean
  Charlotte Russell
  Adam Broome
  Paul Hobson
  Elaine Hobson (Associate)
  Sarah Pryce (Associate)
Clinical Structure within Royal Cornwall Hospital Trust (RCHT)

Surgical Services
Associate Director
Duncan Bliss

Clinical Director Theatre and Anaesthetics
Alison Moore
   Theatres
   Pain
   CSSD
   Anaesthetics
   ICU

Clinical Director T&O
Mark Norton
   Trauma
   Orthopaedics

Clinical Director H&N
Adam Wilde
   OMF
   Ophthalmology
   ENT
   Dermatology

Clinical Director Surgery
Vacant
   GI Surgery
   Urology
   Vascular
   Breast

Women, Children and Sexual Health Services
Associate Director
David Smith

Clinical Director
Karen Watkins
   Obstetrics and Gynaecology
   Sexual Health

Clinical Director Matt Thorpe
   Paediatrics

Medical Services
Associate Director
Sheena Wallace

Clinical Director
Toby Slade
   Emergency medicine

Clinical Director Steve Creely
   Gastroenterology
   Endocrine
   Renal

Clinical Director Gabi Lockwood
   MAU
   Care of the Elderly
   Neurology

Clinical Director Alistair Slade
   Cardiology
   Respiratory

CSCS Services
Associate Director
Karen Jarvill

Clinical Director Bryson Pottinger
   Clinical Imaging
   Medical Physics
   Patient Services
   Pharmacy
   Allied Health Professionals
   Pathology
   RD&I
   Oncology
   Rheumatology
   Haematology
Pathology Directorate Management Structure

Specialty Director
Dr Simon Fleming

HOD CMB
Dr Richard Bendall

HOD Haematology/Blood Transfusion
Dr Adam Forbes

HOD DMP
Dr Robert Jenkins

HOD Clinical Chemistry
Dr Anthea Patterson

CMB Consultants
Dr Chakrabarti Prithwiraj
Dr Andree Evans
Dr Sima Jog

Haematology/Blood Transfusion Consultants
Dr Julie Blundell
Dr M Desmond Creagh
Dr Richard Noble
Dr Elizabeth Parkins
Dr Bryson Pottinger

DMC Consultants
Dr Hugh Jones
Dr Hanne-Britt Smethurst
Dr Ilona Hopkins
Dr Julianne Stolte
Dr Rob Marshall
Dr Tom Grigor
Dr James Garvican
Dr Mihai Chifu
Dr Rasika Singh (Trainee)

Principle Biochemists
Dr Angela Mallard
Anna Barton

Specialty Registrar
Chemical Pathology/Metabolic Medicine
Dr Rachel Cooper

Pathology Quality
and Improvement
Manager and H&S Lead
Dr Anthea Patterson

POCT Clinical Lead
Sarah Pointon

IM&T Manager
Don Hutchison

Phlebotomy Lead
Jeana Curtis

Mortuary Lead
Kevin Hammett

Laboratory Lead
Blood Sciences
and Transfusion
Lead/MHRA Lead
Stephen Bassey

Laboratory Lead
CMB
Simone Girdham

Laboratory Lead
DMP (Clinical)
Valerie Rodd

Laboratory Lead
Cytology
Cathy Winn

Lead BMS
DMP/CMB/HTA
Lead
Peter Helliwell

Laboratory Lead
Clinical Chemistry/Joint reception
Alan Bromley

Pathology Service Manager
Bruce Daniel

Malcolm Owen

Pathology staff
Clinical Chemistry Department Structure

CONSULTANT BIOCHEMIST/HOD
Band 8D
Dr Anthea Patterson

CONSULTANT CHEMICAL PATHOLOGY/SPECIALTY DIRECTOR
Dr Simon Fleming

LABORATORY LEAD
Band 8A
Alan Bromley

SECTION LEAD
POCT
Band 7 (0.7 wte)
Helen Hobba

SECTION LEAD
Manual and Education
Band 7
Susan Hewett

SECTION LEAD
Automation/QL
Band 7
Gina Townsend

BMS/H&S LEAD
Band 6
Alison Thornton

BMS/QL
Band 6 (Vacant)

Trainee BMS (Quality) – Rotational in lab medicine

BMS (Band 5 & Band 6) – fully rotational and to cover 24/7 period as appropriate and as per contract

ASSOCIATE PRACTITIONER
POCT/sends
Band 4

ASSOCIATE PRACTITIONER
Automation Band 4

LABORATORY SUPPORT STAFF
Band 2 and Band 3

JOINT RECEPTION MLA
Clinical Chemistry

SENIOR MLA
Joint Reception
Band 4

JOINT RECEPTION MANAGER
Band 5

BLOOD SCIENCES AND TRANSFUSION LEAD/
MHRA Lead
Band 8B
Stephen Bassey

PRINCIPAL BIOCHEMIST
Band 8A
Dr Angela Mallard
Anna Barton

SPECIALIST REGISTRAR
Dr Rachel Cooper

ASSOCIATE PRACTITIONER
POCT/sends
Band 4

Blood Sciences and Transfusion Lead/
MHRA Lead
Band 8B
Stephen Bassey

CONSORTIUM CHEMICAL PATHOLOGY/SPECIALTY DIRECTOR
Dr Simon Fleming

SPECIALIST REGISTRAR
Dr Rachel Cooper

SENIOR MLA
Joint Reception
Band 4

ASSOCIATE PRACTITIONER
Automation Band 4

LABORATORY SUPPORT STAFF
Band 2 and Band 3

JOINT RECEPTION MLA
Clinical Chemistry

Indicates rotational posts
DMP Department Structure

**HOD**
- Dr Robert Jenkins
  - Consultant Pathologist

**Pathologists**
- Dr Hugh Jones
- Dr Hanne-Brit Smethurst
- Dr Ilona Hopkins
- Dr Juliane Stolte
- Dr Rob Marshall
- Dr Tom Grigor
- Dr James Garvican
- Dr Mihai Chifu

**Trainee Pathologist**
- Dr Rasika Singh

**DMP/CMB/HTA Lead**
- P Helliwell
  - Band 8b

**Dissection LABORATORY LEAD**
- Valerie Rodd
  - Band 8a

**LBMS**
- Band 8a
- Cathy Winn

**Screening Section**
- senior BMS
  - band 7
  - Clare Horne

**Diagnostic Section**
- senior BMS
  - band 7
  - Leonie Glinski

**Routine Senior BMS**
- Band 7
  - Georgina Purvis

**Specials & IT senior BMS**
- Band 7
  - Matthew Coles

**MCBU senior BMS**
- Band 7
  - Mary Jones

**Rotational BMS**
- Band 6 x 4.54

**Rotational BMS Including Trainee**
- Band 5 x 5.0

**Senior MLA**
- Band 4 x 2

**MLA**
- Band 3 x 3.0

**MLSW**
- Band 2 x 5.0

**Indicates rotational posts**

**BMS**
- Band 6 x 3.34

**BMS**
- Band 5 x 1.00

**Cytoscreeners**
- Band 4 x 4.26

**MLSW**
- Band 2 x 3.00

**Administration Manager**
- band 5
  - Natalie Blewett

**Administration Team Leader**
- Band 4 x 2.23

**Administration Secretary**
- Band 3 x 2.60

**Administration Clerk**
- Band 2 x 1.0

**Administration**
- **Senior**
  - Band 5
- **APT Band 5**
  - M Warne, W Drew

**Bereavement**
- **Senior**
  - Band 5
- **Officers**
  - Band 4 x .1.25

**Mortuary Senior**
- **APT Band 5**
- **APT**
  - Band 4 x 1.0

**Bereavement Secretary**
- Band 3 x 0.51

**Bereavement Secretary**
- Band 3 x 1.0

**Mortuary/Bereavement Trainee APT/Bereavement officer**
- Band 3 x 1.0