PATHOLOGY 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 Service.

The Pathology service is comprised of the following departments –

- Diagnostic and Molecular Pathology (DMP) – which comprises of Histopathology, Molecular Cell Biology, Non-Gynaec Cytology, Mortuary and Bereavement service
- Haematology including Andrology and Antenatal Screening
- Blood Transfusion
- Clinical Chemistry (Automated and Manual) including Point of Care (POC)
- Clinical Microbiology (CMB) including Virology and Antenatal Screening
- Phlebotomy services

This QM has been written for all Pathology staff, service users and it describes the QMS across Pathology and also to meet the requirements of International Organization for Standardization (ISO) 15189:2012 and other regulatory requirements i.e. Human Tissue Act (HTA) and Blood safety and Quality Regulations (BSQR). Each section links to a specified ISO 15189:2012 clause and is also compliant to other regulatory bodies as mentioned above. 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.

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 principle documents, all written to ISO standards [shown in square brackets] which describe the principles behind the Pathology procedure which applies to all laboratories across Pathology. These documents are maintained and reviewed by the Pathology Quality and Governance Manager & H&S Lead and approved by the departmental Lab Leads (LL) and Pathology Service Manager (PSM).

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 within Q-Pulse.

The Pathology service has adopted a system of total quality management to facilitate delivery of a high quality analytical, interpretative, and 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 across Pathology 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 and advisory bodies and authorities which oversee areas of the service, including:

• United Kingdom Accreditation Service (UKAS). The Pathology Service is currently accredited to ISO15189:2012 accreditation (Automated Clinical Chemistry and POCT are 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)
• Blood Safety and Quality Regulations 2005
• Care Quality Commission (CQC) - Since 2010 RCHT has been assessed in accordance with CQC standards
• Screening Quality Assurance Services (SQAS) - All screening programmes
• Human Tissue Act (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 Society for Haematology (BSH)
• Royal College of Pathologist (RcPath) Guidelines

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 LAB 1 Reference to Accreditation for Laboratories
UKAS LAB 3 The conduct of UKAS laboratory assessments
UKAS LAB 11 Traceability of Temperature Measurement
UKAS LAB 12
The expression of uncertainty in testing

UKAS LAB 13
UKAS LAB 13 - UKAS Guidance on the Application of ISO/IEC 17025
Dealing with Expressions of Opinions and Interpretations

UKAS LAB 14
In-House Calibrations and Use of Weighing Machines

UKAS LAB 15
Traceability: Volumetric apparatus

UKAS LAB 31
Use of Culture Media Procured Ready-to-use or Partially Completed in
Microbiological Testing

UKAS LAB 39
UKAS LAB 39 - UKAS Guidance on the Implementation and Management
of Flexible Scopes of Accreditation within Laboratories

UKAS LAB 51
Accreditation of multi-site / group laboratories

UKAS LAB 59
Implementation and management of flexible scopes of accreditation for
commissioning of site laboratories

UKAS M3003
The Expression of Uncertainty and Confidence in Measurement

3. TERMS AND DEFINITIONS

BMS: Biomedical Scientist

CA/PA: Corrective Action/Preventative Action

CITS: Cornwall Information Technology Service

Clin: Clinical staff – Clinical Scientist or Consultant

CPD: Continual Professional Development

Datix: Trust incident reporting system

DMP: Diagnostic and Molecular Pathology

EQA: External Quality Assurance

H&S: Health and Safety

HCPC: Health and Care Professions Council

HOD: Head of Department

HTA: Human Tissue Authority

HTC: Hospital Transfusion Committee

IBMS: Institute of Biomedical Science

ICE: Integrated Clinical Environment – GP requesting system

IM&T: Information Management and Technology

IT: Information and Technology

IQC: Internal Quality Control

ISO: International Organization for Standardization

LL: Laboratory Lead

LIMS: Laboratory Information Management System

MR: Management Review

Maxims: Electronic patient record system

MCBU: Molecular Cell Biology Unit

MDT: Multi-disciplinary Team

MHRA: Medicines and Healthcare Products Regulatory Agency

MU: Measurement Uncertainty

PDR: Personal Development Review

PHE: Public Health England

POCT: Point of Care Testing
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 map 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 in the search section.
The Pathology service is a specialty within the Clinical Support Care Group (CSCG) at RCHT.

Pathology Mission Statement

To continue to provide and develop quality, cost-effective Pathology services and staffing relevant to local clinical practice and within a changing technological, functional and organisational environment.

The Pathology Service Manager (PSM) contact details are:

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

For RCH Board, Care Group, Specialty and Department structures please see Appendices
The Pathology Service 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).

5.2 Multi-site Laboratories – TPS 51

The Pathology service at RCHT do not currently have any multi-site laboratories, but DMP do carry out a MOH's frozen section service for Dermatology unit onsite and a EUS and EBUS for the Endoscopy Unit onsite. The mortuary also has a satellite body storage facility held at West Cornwall Hospital.

Pathology also maintains a number of blood fridges outside the laboratory setting.

Please see table 1.1 below for detail.

Table 1.1

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Located</th>
<th>Asset</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatology Unit</td>
<td>Royal Cornwall Hospital for Diagnostic and Molecular Pathology</td>
<td>MOHS Skin frozen section service</td>
<td>Laboratory staff attend Dermatology Unit on an appointment basis to carry out skin frozen sections for MOH’s. The slides are returned to the laboratory for staining and diagnosis.</td>
</tr>
<tr>
<td>Endoscopy Unit</td>
<td>Royal Cornwall Hospital for Diagnostic and Molecular Pathology</td>
<td>EBUS – ROSE Endobronchial Ultrasound guided fine needle aspirations – rapid on site evaluation EUS – ROSE Endoscopic ultrasound guided fine needle aspirations – rapid on site evaluation</td>
<td>Laboratory staff attend Endoscopy Unit on an appointment basis to carry out EBUS and EUS diagnostic procedures. The slides are returned to the laboratory for staining and diagnosis.</td>
</tr>
<tr>
<td>Body Store</td>
<td>West Cornwall Hospital</td>
<td>Body storage only – satellite unit</td>
<td>Mortuary staff attend WCH on an appointment basis to release deceased and to support viewings</td>
</tr>
<tr>
<td>West Cornwall Hospital</td>
<td>Royal Cornwall Hospitals Trust St Clare Street, Penzance, TR18 2PF</td>
<td>Blood fridge room in renal corridor (x1)</td>
<td>Kelsius temperature monitoring is managed within the Blood Transfusion department. Service and maintenance of Asset is dealt with by Pathology Quality and Governance Manager</td>
</tr>
<tr>
<td>St Michael's Hospital</td>
<td>Royal Cornwall Hospitals Trust Trelissick Road, Hayle, TR27 4JA</td>
<td>Blood fridge Theatre reception</td>
<td>Kelsius temperature monitoring is managed within the Blood Transfusion department. Service and maintenance of Asset is dealt with by Pathology Quality and Governance Manager</td>
</tr>
<tr>
<td>Duchy Hospital Ramsay Healthcare</td>
<td>Penventinnie Lane, Truro, TR1 3UP     Clinical</td>
<td>Blood fridge Clinical store room</td>
<td>Kelsius temperature monitoring is managed within the Blood Transfusion department. Service and maintenance of Asset is dealt with by Pathology Quality and Governance Manager</td>
</tr>
<tr>
<td>store room</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>----------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>within the Blood Transfusion department. Service and maintenance of Asset is dealt with by Pathology Quality and Governance Manager</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 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>08.00 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>
<td></td>
<td>17:15 to 08:45</td>
<td></td>
<td>HTA / Management cover On-Call No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 08.00 to 12.30</td>
<td>1 x BMS 08.00 to 12.30</td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>1 x MLA 08.00 to 12.30</td>
<td>1 x MLA 08.00 to 12.30</td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>1 x MLA 08.00 to 12.30</td>
<td>1 x MLA 08.00 to 12.30</td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td><strong>Saturday</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 08.00 to 20.00</td>
<td>1 x BMS 08.00 to 20.00</td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 08.00 to 20.00</td>
<td>1 x BMS 08.00 to 20.00</td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td><strong>Sunday</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td>(&amp; Bank Holidays)</td>
<td>1 x BMS 08.00 to 20.00</td>
<td>1 x BMS 08.00 to 20.00</td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>1 x BMS 08.00 to 20.00</td>
<td>1 x BMS 08.00 to 20.00</td>
<td></td>
<td></td>
<td>1 x APT On-Call No Consultant Cover</td>
</tr>
<tr>
<td></td>
<td>1 x MLA 08.00 to 15.00</td>
<td>1 x MLA 08.00 to 15.00</td>
<td></td>
<td></td>
<td>1 x APT On-Call 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 Management team are:

- Specialty Director (SD)
- PSM
- Head of Department (HOD)
- Lead Scientist (LS)
- Laboratory Leads (LL)
- Business Manager
- Medical Consultants
- Pathology Quality and Governance Manager and H&S Lead
- Pathology Improvement and Assessment Specialist
- Pathology IT Manager

The Pathology Service management meeting is conducted monthly as two separate meetings. These include –

- Pathology Business Meeting
- Pathology Quality and Governance Meeting

The minutes for both meetings can be found at the following address -

Pathology Business Meeting
S:\RCH-HistoBio-Everyone\Pathology Directorate Business

Pathology Quality and Governance Meeting
S:\RCH-HistoBio-Everyone\Pathology Directorate Quality Governance & Improvement Meeting

The meetings are 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.

Pathology Directorate – Business – PA-GEN-POL-11
Pathology Directorate – Quality and Governance – PA-GEN-POL-12
<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 James Garvican</td>
<td>The SD has responsibility for the effective leadership, operation and administration of Pathology. The SD is accountable to the Clinical Director and works closely with the PSM on the strategic development and modernisation of Pathology. The SD needs to be clinically competent and carry out managerial duties assigned to him/her which is ascertained through consultant competency and PDR. See Job description - PA-GEN-JD-10</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 Clinical Support Care Group General Manager.</td>
</tr>
<tr>
<td>HOD</td>
<td>Dr James Garvican (DMP)</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>
<tr>
<td></td>
<td>Dr Andree Evans (CMB)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr Adam Forbes (Haematology/Blood Transfusion)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr Anthea Patterson (Clinical Chemistry)</td>
<td></td>
</tr>
<tr>
<td>LBMS/LS</td>
<td>Alain Rolli (Blood Transfusion, Haematology/Clinical Chemistry/MHRA Lead)</td>
<td>Report to the PSM. Budget planning and financial management. Ensure compliance with regulatory agencies, administrative officials. Relate and function effectively with the healthcare community and patient population. 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.</td>
</tr>
<tr>
<td></td>
<td>Stephen Davison (DMP and HTA Lead, Quality Lead)</td>
<td>Implementation of a safe laboratory facilities</td>
</tr>
<tr>
<td></td>
<td>Gemma Vanstone (Clinical Microbiology and</td>
<td></td>
</tr>
<tr>
<td>Virology) 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 essential services are available during emergency situations or conditions where services are limited or unavailable. HR management of staff. Deputies for the PSM.</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>LL</strong> (<em>Delegation may vary between individuals – please see specific job descriptions for details)</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Ian Sullivan** (Blood Transfusion)  
**Martyn Hicks** (Haematology)  
**Lisa Vipond** (Clinical Chemistry)  
**Val Rodd** (DMP)  
**Clinical Histology**  
**Gemma Vanstone** (Clinical Microbiology)  
**Herty Nарcho** (Clinical Virology) |
| Reporting to the LBMS/LS. 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. |
| **Business Manager (IT, Quality and Optimisation teams)**  
**Adrian Caley** |
<p>| 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. Ensure there are appropriate numbers of competent staff to meet service user requirements. Implementation of the quality policy. Define, implement and monitor standards of performance and quality improvements. Address any request, complaint or suggestion from staff or service user. |</p>
<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Governance Leads</td>
<td>Dr Rob Jenkins (DMP)</td>
<td>Facilitating and documenting clinical governance issues and implementing service improvements for clinical roles and systems.</td>
</tr>
<tr>
<td>Clinical Audit Leads</td>
<td>Dr David Tucker (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 Tim Bracey (DMP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vacant * – CMB</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr Anthea Patterson (Clinical Chemistry)</td>
<td>*Deputy = Clinical Microbiologist Team will cover post until position is filled</td>
</tr>
<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>
<td></td>
</tr>
<tr>
<td></td>
<td>Bruce Daniel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Val Rodd</td>
<td></td>
</tr>
<tr>
<td>Clinical Education Leads</td>
<td>Dr Adam Forbes (Haematology/Blood Transfusion)</td>
<td>Plan and direct research where appropriate.</td>
</tr>
<tr>
<td></td>
<td>Dr James Garvican (DMP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vacant* – CMB</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr Anthea Patterson (Clinical Chemistry)</td>
<td>*Deputy = Clinical Microbiologist Team will cover post until position is filled</td>
</tr>
<tr>
<td>Pathology Training Lead</td>
<td>Martyn Hicks</td>
<td>Co-ordinates the training programme across Pathology</td>
</tr>
<tr>
<td>Training officers</td>
<td>Martyn 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>Val Rodd (DMP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gemma Vanstone (CMB)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr Anthea Patterson (Clinical Chemistry)</td>
<td></td>
</tr>
<tr>
<td>Complaints Officers</td>
<td>Martyn Hicks (Haematology/Blood Transfusion)</td>
<td>Address any complaint from staff or service users.</td>
</tr>
<tr>
<td>Human Resources (HR) Leads</td>
<td>Martyn Hicks (Haematology/Blood Transfusion)</td>
<td>Accountable to LBMS. Advise and facilitate HR issues in accordance with Trust policies.</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Valerie Rodd (DMP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gemma Vanstone/Herty Narcho (CMB)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lisa Vipond (Clinical Chemistry)</td>
<td></td>
</tr>
<tr>
<td>HR Investigators</td>
<td>Martyn Hicks (Haematology/Blood Transfusion)</td>
<td>Staff that have attended the Trust HR investigator training can be assigned formal HR investigations.</td>
</tr>
<tr>
<td></td>
<td>Lisa Vipond (Clinical Chemistry)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Valerie Rodd/ Leonie Glinski/ Georgina Purvis (DMP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gemma Vanstone/Herty Narcho (CMB)</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 Pathology and CSCG on H&amp;S issues.</td>
</tr>
<tr>
<td>Departmental H&amp;S Leads</td>
<td>Val Rodd (DMP)</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></td>
<td>Deborah Wadham (CMB)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Louise Simon (Clinical Chemistry)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Interim</td>
<td></td>
</tr>
<tr>
<td>Position</td>
<td>Responsibilities</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
| Human Tissue Authority (HTA)     | Human Tissue Authority (HTA) Designated Individual (DI)  
Stephen Davison  
(DMP)  
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. |
| HTA Person designated (PD) for Histology | Georgina Purvis, Matthew Coles  
Val Rodd  
(DMP)  
Kevin Hammett  
(Mortuary)  
Responsibilities are delegated from HTA DI. The PDs 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. |
| Information Management and Technology (IM&T) Manager | Steve Sprague  
Oversee the IM&T systems within Pathology including Maxims, WinPath and Q-Pulse. Supervise the Pathology IM&T team. Maintain the required messaging and coding to keep the system current and efficient. To support Pathology services performance and users by providing timely data and information. To produce data files as required for Freedom of Information and Trust legal team requests. |
| Departmental IM&T Leads         | Matt Coles (DMP)  
Kathy Pollard (CMB)  
Providing computer systems supervision to include implementation, management and support. |
| POCT Lead                       | Lisa Vipond  
(Clinical Chemistry)  
Helen Hobba  
(Clinical Chemistry)  
Oversee the day-to-day running of the POCT service within the Trust and Community |
| Breast Screening Lead           | Dr Robert Jenkins  
(DMP)  
Oversee compliance and data submission / audit for the NHS Breast Cancer screening programme. |
| Bowel Cancer screening lead      | Dr Ilona Hopkins  
(DMP)  
Oversees compliance and data submission / audit for the NHS Bowel Cancer screening programme. |
| Foetal Anomaly Laboratory Lead   | Dr Anthea Patterson  
Has overall responsibility of receipt and sending of foetal anomaly samples, reporting of results where required, and attend quarterly trust clinical governance meetings |
| Antenatal Serology Lead         | Vacant * - (CMB)  
Has responsibility of receipt and examination of antenatal serology, reporting of results where required, and attend quarterly trust clinical governance meetings |
<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deputy Clinical Microbiologist Team</td>
<td>Dr Michelle Furtado</td>
<td>Has responsibility of receipt and examination of Antenatal sickle cell and thalassaemia screening, reporting of results where required, and attend quarterly trust clinical governance meetings</td>
</tr>
<tr>
<td>Local lead for Antenatal Sickle cell and thalassaemia screening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathology Quality and Governance Manager and H&amp;S Lead</td>
<td>Sarah Pointon</td>
<td>Accountable to the Business Manager. Oversees the Pathology QMS, including management of Datix incidents. Oversees Pathology Governance.</td>
</tr>
<tr>
<td>Pathology Improvement and Assessment Manager</td>
<td>Lynne Bedford</td>
<td>Accountable to the Business Manager. Oversees the Pathology improvement projects, validation and verification.</td>
</tr>
<tr>
<td>QL</td>
<td>Teresa Vercoe</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 Pathology Quality and Governance Manager and H&amp;S Lead and the other departmental QL. Ensure the implementation of the quality policy.</td>
</tr>
<tr>
<td></td>
<td>Lindsey Vincent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Matthew Coles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vacant* (Clinical Chemistry)</td>
<td></td>
</tr>
</tbody>
</table>

*Deputy = Clinical Microbiologist Team will cover post until position is filled

5.2. Legal entity (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 (See PA-GEN-EX-34). 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

5.3. Ethical conduct (ISO Clause 4.1.1.3) (Formally Annex C)

The ethical conduct expected of staff within Pathology is outlined in the Trust Dignity at work Policy which can be found on the Trust document library and also the Health and Care
Professionals Council (HCPC) standards of conduct, performance and ethics policy [PA-GEN-EX-8].

These documents cover:

- RCHT including the Pathology service has no involvement in any activities that would diminish confidence in the laboratory’s competence, impartiality, 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
- Biomedical Scientist (BMS) staff must be registered with the 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 wrongdoing 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 the Pathology Service.

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 1.2. Where individuals are not named the responsibility remains with the SD.

The SD is supported closely by the PSM 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 EQA schemes. These are checked in the SD annual Personal Development Review (PDR).
5.5. Management Responsibility and Commitment (ISO Clause 4.1.2 & 4.1.2.1)

The Pathology 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 1.3)
- Quality training and competency
- Feedback from Management Review (MR)
- Feedback from service users survey
- Quality policy (Section 5.7)
- Pathology Quality and Governance Manager and Health and Safety Lead (Section 5.9)

Quality objectives are set annually at the MR which also includes the Pathology business objectives. 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, 5.5 and 5.7)

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 Care Group level:

- Service user survey (Distributed annually)
- User communications and user information
- Patient engagement via patient ambassadors
- Monitoring Turnaround Times
- EQA participation
- Findings from external and internal audits
- Regular review of Pathology user Guide
- Regular 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 Care Group 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
- Assistance with sample preservation and collection training (Cytology fine needle aspirations)
- Glucose monitoring (and other POCT) Training
- Generic Emails
- Production of lab med news
- Interpretative comments added to reports

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 MR by the Pathology Management Team.

The Quality Policy is written as a separate controlled document and signed by the SD. 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.

5.8. Quality objectives and Planning (ISO Clause 4.1.2.4, 4.12 & 4.15)

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

The pan-pathology objectives are agreed by the Pathology management team and progress/action plans with the previous objectives are discussed at the MR.

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 1.2 for responsibilities of key roles (e.g. Lead BMS, QL, and H&S Lead).

Organisational structures for Care Group and Pathology Service 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 process and 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 1.3, 1.4, 1.5, 1.6, 1.7 and 1.8.

Communication to service users regarding pre-examination, examination and post-examination processes issues/changes is achieved through a variety of mechanisms including:-

- Website
- News bulletins/newsletters
- User satisfaction surveys
- Resolution of complaints and incidents
- Documented policies and procedures including Pathology User Guide, Pathology Quality manual and Pathology Quality Policy which are available on the Trust Internet or on ICE.

### Table 1.3

**Clinical Support Care Group**

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Frequency</th>
<th>Attendees</th>
<th>Aims</th>
<th>Minutes recording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Support Care Group Management meeting</td>
<td>Monthly</td>
<td>Clinical Director (chair) General Manager PSM Care Group governance lead Care group managers including HR, Finance and patient services Clinicians</td>
<td>To discuss monitor and progress the operational and strategic aims and activity of the Care group</td>
<td>S:\TR13\Clinical Support Services Cancer\Meetings\Groups\DMB meetings\2016 DMB Meeting Papers</td>
</tr>
<tr>
<td>Clinical Support Care Group Governance Huddle</td>
<td>Weekly</td>
<td>General Manager (chair) Care Group governance lead Pathology Quality and Governance Manager and H&amp;S Lead Care Group Governance Leads</td>
<td>To discuss Care Group governance issues</td>
<td>S:\TR13\Clinical Support Services Cancer\Governance\Gov DMB</td>
</tr>
</tbody>
</table>

### Table 1.4

**Pan-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>Pathology Business Directorate Meeting</td>
<td>Monthly</td>
<td>PSM (chair) Pathology Service director 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 Service</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>Pathology Quality and Governance Committee</td>
<td>Monthly</td>
<td>PSM (chair) Pathology Service director Pathology Quality and Governance Manager and H&amp;S Lead Laboratory Leads</td>
<td>To discuss, confirm, review and action governance and quality issues and reports related to the Pathology Service</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>Pathology Quality and Governance Manager and H&amp;S Lead (Chair) Department H&amp;S Leads Laboratory Leads 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>MR (all specialties)</td>
<td>Annual</td>
<td>Pathology Quality and Governance Manager and H&amp;S Lead Senior BMS / Medical Staff, QL, staff representative</td>
<td>To discuss Pathology quality issues and achievements/compliments in the past year</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
</tbody>
</table>
**Bi-directional communication (Pathology and RCHT)**

- Communication filtered down from Trust Board
- Communication escalated to Trust Board

---

**Trust Governance/H&S Committee**

---

**Care Group Management meeting/Governance Huddle via Quality KPI and escalation**

---

**Pathology Service Management Meeting//Pathology Quality and Governance Committee**

---

**Pathology H&S Group**

---

**Departmental meetings including Management and laboratory staff meetings**
<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)</td>
<td>Meets up to 4 times a year</td>
<td>Consultant Biochemist (Chair) Lead 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>POCT (Pathology working Group)</td>
<td>Monthly</td>
<td>Consultant Clinical Chemist, Senior BMS - Chemistry POCT, Assistant Practitioner, Pathology Quality and Improvement Manager, Pathology IT Manager, Chem BMS 6, Senior BMS - Haem Automation, Senior BMS - Haem Coagulation, Pathology Service Manager.</td>
<td>To discuss point-of-care testing and allocate appropriate actions to follow up any issues arising.</td>
<td>CHEMISTRY\Meetings\Chemistry POCT meetings</td>
</tr>
<tr>
<td>Senior Management and Quality Meeting</td>
<td>Bi-Monthly</td>
<td>HOD, Clinical Scientists, Laboratory Lead, Section seniors, QL, Joint Reception Manager, QM</td>
<td>To discuss strategy, quality issues and objectives, IOC, QA, EQA, Operational overview of department.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES S:\RCH-HistoBio-BioChem\CHEMISTRY\Meetings\Senior Management &amp; Quality Meetings</td>
</tr>
<tr>
<td>Clinical Chemistry Clinical Approval (CAPP) meetings</td>
<td>Monthly</td>
<td>HOD, Consultant Clinical Chemist, Specialist Registrar, Principal Clinical Scientists, Senior Clinical Scientists and Trainee Clinical Scientist</td>
<td>To discuss clinical approval issues, new guidelines, departmental clinical discussions, peer review.</td>
<td>CHEMISTRY\Meetings\Chemistry CAPP meetings</td>
</tr>
<tr>
<td>Chemistry Department Meeting</td>
<td>Monthly (Post Care Group meeting)</td>
<td>All staff in Chemistry Trust Communications, Quality, H&amp;S</td>
<td></td>
<td>CHEMISTRY\Meetings\Chemistry Department 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>
<tr>
<td>Team Huddles</td>
<td>Weekly</td>
<td>Senior staff</td>
<td>Day to day running issues, Quality, H&amp;S</td>
<td>CHEMISTRY\Meetings\Chemistry \Huddles</td>
</tr>
<tr>
<td>MDT Meetings</td>
<td>Monthly</td>
<td>Relevant MDT Team members including specialty Consultants, specialty registrar and nurse specialist</td>
<td></td>
<td>List of patients discussed in the meeting</td>
</tr>
<tr>
<td>Pituitary</td>
<td>Adrenal</td>
<td>Endocrine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 1.5**

**Clinical Chemistry**

<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)</td>
<td>Meets up to 4 times a year</td>
<td>Consultant Biochemist (Chair) Lead 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>POCT (Pathology working Group)</td>
<td>Monthly</td>
<td>Consultant Clinical Chemist, Senior BMS - Chemistry POCT, Assistant Practitioner, Pathology Quality and Improvement Manager, Pathology IT Manager, Chem BMS 6, Senior BMS - Haem Automation, Senior BMS - Haem Coagulation, Pathology Service Manager.</td>
<td>To discuss point-of-care testing and allocate appropriate actions to follow up any issues arising.</td>
<td>CHEMISTRY\Meetings\Chemistry POCT meetings</td>
</tr>
<tr>
<td>Senior Management and Quality Meeting</td>
<td>Bi-Monthly</td>
<td>HOD, Clinical Scientists, Laboratory Lead, Section seniors, QL, Joint Reception Manager, QM</td>
<td>To discuss strategy, quality issues and objectives, IOC, QA, EQA, Operational overview of department.</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES S:\RCH-HistoBio-BioChem\CHEMISTRY\Meetings\Senior Management &amp; Quality Meetings</td>
</tr>
<tr>
<td>Clinical Chemistry Clinical Approval (CAPP) meetings</td>
<td>Monthly</td>
<td>HOD, Consultant Clinical Chemist, Specialist Registrar, Principal Clinical Scientists, Senior Clinical Scientists and Trainee Clinical Scientist</td>
<td>To discuss clinical approval issues, new guidelines, departmental clinical discussions, peer review.</td>
<td>CHEMISTRY\Meetings\Chemistry CAPP meetings</td>
</tr>
<tr>
<td>Chemistry Department Meeting</td>
<td>Monthly (Post Care Group meeting)</td>
<td>All staff in Chemistry Trust Communications, Quality, H&amp;S</td>
<td></td>
<td>CHEMISTRY\Meetings\Chemistry Department 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>
<tr>
<td>Team Huddles</td>
<td>Weekly</td>
<td>Senior staff</td>
<td>Day to day running issues, Quality, H&amp;S</td>
<td>CHEMISTRY\Meetings\Chemistry \Huddles</td>
</tr>
<tr>
<td>MDT Meetings</td>
<td>Monthly</td>
<td>Relevant MDT Team members including specialty Consultants, specialty registrar and nurse specialist</td>
<td></td>
<td>List of patients discussed in the meeting</td>
</tr>
<tr>
<td>Pituitary</td>
<td>Adrenal</td>
<td>Endocrine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table 1.6
#### 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>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/Daily team huddle</td>
<td>Daily</td>
<td>All staff (excluding the consultants)</td>
<td>Discuss daily lab issues, feedback from staff and LMT debrief</td>
<td>Email is sent out daily as well as a printout onto the board for the week.</td>
</tr>
</tbody>
</table>

### Table 1.7
#### 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 and Management Group (DQMG)</td>
<td>Monthly</td>
<td>Clinical Governance Lead, SD, Laboratory Lead, Chief BMSs, Section Leads, QL, Deputy QL, Clinical Audit Lead, PQIM</td>
<td>Monitor quality in all departmental sections. Improvements and ISO requirements. Review new developments and DMP specific issues</td>
<td>Agenda Q Pulse Pathology Meeting Form Minutes Q Pulse PA-MINUTES</td>
</tr>
<tr>
<td>DMP Staff Council meetings</td>
<td>Bi-Monthly</td>
<td>SD, Laboratory Lead, DMP seniors, representation from all staff groups across DMP to include: Histology, Cytology, MCBU, Office, Mortuary, Bereavement</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>Research, Development and Innovation (Trials)</td>
<td>Bi-Monthly</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 TEDI/TERA</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 Diary (Tower block labs)</td>
</tr>
<tr>
<td>Multi-Disciplinary Team (MDT) Meetings</td>
<td></td>
<td></td>
<td></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>
</tr>
<tr>
<td>1. Renal</td>
<td>Monthly</td>
<td>Relevant MDT Team members including specialty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Haematology</td>
<td>Weekly</td>
<td>Consultant Pathologist representative from</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Dermatology</td>
<td>Weekly</td>
<td>Pathology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Upper GI (GG)</td>
<td>Weekly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Upper GI (HPB)</td>
<td>Weekly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Breast</td>
<td>Weekly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Gynaecology</td>
<td>Weekly</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8. Urology
9. Dermatology CPC
10. Endocrine/Thyroid
11. Head and Neck
12. Lower GI
13. Colposcopy
14. Anal
15. Lung

8. Weekly
9. Fortnightly
10. Fortnightly
11. Weekly
12. Monthly
13. Monthly
14. Monthly
15. Weekly

RCHT HTA Reporting Structure

Kate Shields
Chief Executive

Medical Director
License Holder

DI and LBMS
DMP
Mr Stephen Davison

Care Group Clinical Director
Hannah Falvey

Care Group Manager
Richard Andrzejuk

Person Designate
Mortuary Manager
Mr Kevin Hammett

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

Person Designate Consultant Obstetrics and Gynaecology
Rob Holmes

Person Designate Consultant Paediatrician
Andrew Collinson
<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,</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 Huddle</td>
<td>Daily</td>
<td>All staff</td>
<td>Day to day running issues, Quality, H&amp;S</td>
<td>S:\RCH-HistoBio-Haem\Quality records - A\Retention of Records\Huddle Meetings + Fire Safety checks</td>
</tr>
<tr>
<td>Haematology/Blood Transfusion Laboratory Meeting</td>
<td>Fortnightly</td>
<td>All Staff</td>
<td>Actions arising and Care Group information. Lab issues.</td>
<td>G:\Personnel - B\MEETINGS\LAB MEETINGS</td>
</tr>
<tr>
<td>Haematology MLA Meeting</td>
<td>Monthly</td>
<td>Haematology Lab Lead, MLA’s</td>
<td>Actions arising and Lab issues.</td>
<td>G:\Personnel - B\MEETINGS\LAB MEETINGS</td>
</tr>
<tr>
<td>Transfusion Management Group Meetings</td>
<td>Weekly</td>
<td>Blood transfusion senior staff</td>
<td>Blood transfusion Steering Group</td>
<td>G:\Blood TransfusionTMG meetings</td>
</tr>
<tr>
<td>Hospital Transfusion Team (HTT)</td>
<td>Monthly</td>
<td>Laboratory Lead, Clinical consultant, transplant Practitioner, consultant anaesthetist</td>
<td>Is the executive group of the HTC</td>
<td>G:\Blood TransfusionHTT</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>Trust Transfusion business and education meetings</td>
<td>G:\Blood TransfusionHTC</td>
</tr>
<tr>
<td>Andrology and Cornwall Centre for Reproductive Medicine</td>
<td>3-6 monthly</td>
<td>Obs and Gynae consultants, fertility nurses and Andrology lead</td>
<td>To ensure a safe robust andrology service</td>
<td>S:\RCH-HistoBio-Haem\Coagulation</td>
</tr>
<tr>
<td>PHE Cornwall Antenatal and New-born Screening Programme Governance Board Meetings</td>
<td>6 monthly</td>
<td>Obs and Gynae Consultant, antenatal co-ordinators, Clinical Chemistry consultant, Lab lead abnormal Haemoglobins, Microbiology consultant, PHE, sonographer, Matron, midwife plus representatives from across the screening programme at RCHT and PHE</td>
<td>To review procedures across the screening programme</td>
<td>S:\RCH-HistoBio-Haem\Coagulation</td>
</tr>
<tr>
<td>Antenatal Screening Operational Group meetings</td>
<td>6 monthly</td>
<td>Obs and Gynae Consultant, antenatal co-ordinators, Clinical Chemistry consultant, Lab lead abnormal Haemoglobins,, Microbiology consultant, PHE, sonographer, Matron, midwife</td>
<td>To ensure a safe robust antenatal service</td>
<td>S:\RCH-HistoBio-Haem\Coagulation</td>
</tr>
</tbody>
</table>
5.10. Pathology Quality and Governance Manager (ISO Clause 4.1.2.7)

The Pathology Quality and Governance Manager is accountable to the Business Team Manager and their job description is available on Q-Pulse [PA-GEN-JD-1].

The Pathology Quality and Governance Manager works closely with the Pathology Quality Improvement and Assessment Specialist and together they oversee the Pathology QMS, facilitate compliance with regulatory authorities, quality improvement and ensure that the QMS functions efficiently and effectively with the use of Q-Pulse.

The Pathology Quality and Governance Manager liaises with the Care Group governance lead and attends the weekly Care Group governance huddle and the quarterly Care Group H&S meeting escalating any quality, governance or H&S issues within Pathology.

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

The majority of the Pathology wide documents are written and reviewed by the Pathology Quality and Governance Manager and then approved by the Pathology Management. The exceptions to this are 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.

5.11. Quality Management System (ISO Clause 4.2, 4.2.1, 4.2.2 & 4.2.2.1)

The Pathology service 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.

Each department holds monthly senior staff meetings (or specific quality meetings) which discuss quality within their department.

Quality Indicators are also discussed at the Pathology management meeting to ensure there are no issues within Pathology that may require escalation to Care Group.

Quality Indicators recorded include the following and there is a Pathology policy regarding KPI's [PA-GEN-POL-9] –

- Number of Incidents e.g. Datix incidents and serious incidents
- Number of complaints/claims
- Mandatory training
- PDR compliance
- Clinisys uptime
- TAT
- Mortuary capacity
- Overdue blood film requests
- % MDT attended by Pathologists
- Platelet/red cell wastage
- Integrated Clinical Environment (ICE) requests
- Regulatory compliance
- Document library overdue documents
- EQA compliance
- Q-Pulse KPI's
- Risks

Anything that requires escalation from the departments is reported to the Pathology Quality, Governance Manager and H&S Lead or discussed at the monthly Pathology Management Meeting. Any issues are then escalated to the Care Group via the Pathology Quality and Governance Manager and the Pathology Management if required.

The principles of the QMS are communicated to staff by various ways, including Pathology Principle Documents, Departmental Induction Manual, QMS training and QMS competency for all staff. These documents are sent out to all staff on Q-Pulse, who then acknowledges them as evidence to show they are up to date.

[Refer to Preparation and Control of Documents [PA-GEN-SOP-16] and Q-Pulse Intermediate and Power User Manual - Document Control [PA-TRAIN-MAN-7].

5.12. 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 it also provides information for service users, including accreditation bodies, e.g. UKAS, MHRA, HTA 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 principle documents comply with all regulations e.g. UKAS, HTA and MHRA and they are audited over a 2 year period against ISO 15189. The audits cover both Pan-pathology and departmental compliance.

These principle documents include –

- Principles of Business Continuity Planning [PA-QMS-PD-1]
- Principles of Document Control [PA-QMS-PD-2]
- Principles of Control of Records [PA-QMS-PD-3]
- Principles of Personnel Management [PA-QMS-PD-4]
- Principles of Environmental Control [PA-QMS-PD-5]
- Principles of Equipment and Reagent Management [PA-QMS-PD-6]
- Principles of Risk Management, Incident Management and Continual Improvement [PA-QMS-PD-7]
- Principles of Procurement, including the relationship between Pathology and external services [PA-QMS-PD-8]
• Principles of Pathology Transportation [PA-QMS-PD-9]
• Principles of Pre-examination processes [PA-QMS-PD-10]
• Principles of Change Control [PA-QMS-PD-11]
• Principles of Measurement of Uncertainty [PA-QMS-PD-12]
• Principles of review, report and release of results [PA-QMS-PD-13]
• Principles of storage, retention and disposal of clinical material [PA-QMS-PD-14]
• Principles of Quality Control and Assurance [PA-QMS-PD-15]
• Principles of Internal Audit [PA-QMS-PD-16]
• Principles of Laboratory Information Management [PA-QMS-PD-17]

These documents are managed by the Pathology Quality and Governance Manager and Health and Safety Lead and are approved by the LL.

Other Pathology documents include -

• Laboratory Health and Safety Manual [PA-HS-MAN-1]
• Management of Internal and External Complaints and User feedback Within Pathology [PA-QMS-SOP-4]
• Pathology Laboratory information management system (LIMS) [PA-GEN-SOP-8]
• Preparation and control of documents [PA-GEN-SOP-16]
• Recording and managing nonconformities and incidents [PA-QMS-SOP-3]
• Referrals to and from external laboratories [PA-GEN-SOP-26]
• Specimen Acceptance and Rejection Policy [PA-GEN-POL-1]
• Training Policy [PA-TRAIN-POL-3]
• Pathology User guide [PA-GEN-MAN-2]
• Trust Health & Safety Policy [PA-HS-EX-15]

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

The QM 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 [PA-QMS-MAN-1].

5.13. 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. This ensures that all documents are reviewed and approved by relevant personnel before they are issued.

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.
5.14. **SLA (ISO Clause 4.4, 4.4.1 & 4.4.2)**

The procedure for the selection and purchasing of external services and establishing SLAs is documented in:

- Principles of Procurement, including the relationship between Pathology and External Services [PA-QMS-PD-8]
- RCHT Templates which includes templates for – Trust as the commissioner, Trust as the provider and 2 way SLA template [PA-GEN-EX-7]

RCHT does not require SLAs between service users within RCHT. The exception is Blood transfusion which has an SLA with St Michael’s Hospital and West Cornwall Hospital regarding the supply of blood and blood products.

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

5.15. **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 Principle Document – Principles of Procurement and the Relationship between Pathology and External Services [PA-QMS-PD-8]. This document describes the specific criteria for the choosing of the relevant referral laboratory.

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

5.16. **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 –

- Principles of Procurement, including the relationship between Pathology and External Services [PA-QMS-PD-8]
- Change control using Q-Pulse CA/PA module [PA-GEN-SOP-36]

A list of approved suppliers of equipment, reagents and consumables is kept within the Trust Electronic Requesting Ordering Service system – UNIT 4.

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

The performance of these suppliers is monitored annually in the MR, 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.
5.17. 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://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/Pathology/PathologyUserGuide.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 2500
- Clinical Chemistry - 01872 25 2540/2548/3047
- 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.

5.18. 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]. A complaint is detailed as any expression of dissatisfaction or issue that requires response or action.

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.

Information regarding formal complaints is sent from the Trust complaints team/PALS Team/Care Group and assigned to a trained investigating office within Pathology.

Investigations and action / resolutions plans are completed within set time frames and returned to the complaints team and Governance Manager within the Care Group.

All formal complaints are reviewed at the monthly departmental meetings and also at the Pathology Quality and Governance meeting.

5.19. 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]

Any non-conformity that has been raised from audits, staff actions, meetings, errors or external visits e.g. HSE, MHRA RCHT 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. A monthly audit is also carried out to detect any CA/PA trends across Pathology. These audits can be found on Q-Pulse in the audit module and the findings from this audit are then discussed at the Pathology Quality and Governance Meeting.

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.

A monthly audit is also carried out to detect any incident trends across Pathology and also a root cause for each incident is recorded. These audits can be found on Q-Pulse in the audit module and the findings from this audit are then discussed at the Pathology Quality and Governance Meeting.
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.

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

A weekly audit is also carried out to detect any datix incident trends across Pathology and also a root cause for each incident is recorded. This is reported in the weekly Care Group Governance huddle and also at the monthly Pathology Quality and Governance Meeting.

5.20. 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 [PA-GEN-LI-55]

Types of CA/PA’s include:

- Meeting actions
- Individual Staff 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

The type of CA/PA and when it is used can be found in Recording and managing nonconformities and incidents [PA-QMS-SOP-3].

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 monthly by the Pathology Quality and Governance Manager).
5.21. **Continual Improvement (ISO Clause 4.12)**

The Pathology Service 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:

- Risk management
- Service user and staff suggestions
- Incidents
- Error logs
- CA/PA’s
- Review of progress with objectives
- Quality management meetings
- Audit
- Management Reviews

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.

5.22. **Control of records (ISO Clause 4.13)**

The principles of control of records are described in Principles of Control of Records [PA-QMS-PD-3].

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.


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

- Q-Pulse Training Manual - Audit Module [PA-TRAIN-MAN-8]
- Principles of Internal Audit [PA-QMS-PD-16]

These documents cover key areas including:
• Periodic review of requests and suitability of procedures and sample requirements including sample volume, preservative requirements, insufficient or excessive amounts of sample collected
• Assessment of user feedback
• Staff suggestions (See section 5.25)
• Internal audit
• Risk management
• Quality indicators
• Review by external organisations

The Pan-pathology audits are scheduled and performed by the Pathology Quality and Governance Manager over a 2 year period and are audited to comply with ISO15189 standards and are focused on Pathology wide generic principle documents and the QMS.

The principle documents are written to comply with the ISO 15189 and regulatory standards and Trust requirements and they provide the framework for the specific departmental document which are audited against these principle documents to ensure compliance.

The results from each of the audits are discussed and agreed with the specific department Laboratory Lead if any findings are raised against them.

Only competent staff or staff that are 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 within the department 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 (demand management). These audits are then scheduled and recorded in Q-Pulse audit module.

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

A Pathology user survey is sent out 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 written against all processes carried out in the departments or written against COSHH and 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 are reviewed by the review date by the Pathology Quality and Governance Manager and LL and are escalated to Care Group meetings if required.

Any new risks or changes in these risks are ratified at the Pathology Governance and Quality Committee before being escalated to the Care Group.

5.24. 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.

5.25. Management review (ISO Clause 4.15)

Approach to the Pathology MR
The Pathology MR is conducted every 12 months and takes place as a pan-pathology review. The information is captured in the MR template and feedback is communicated to staff via staff meetings by the LL. 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 MR and agreed within the Pathology Quality and Governance meeting. These are available on Q-Pulse in the audit module.

5.26. Personnel (ISO Clause 5.1.1-5.1.9)

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:

- Pathology 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

LL 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 (RCPPath). Staffing levels are monitored against compliance with turnaround times and key performance indicators.

Staff records are maintained according to Information Security Management: NHS Code of Practice. 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 within staff P:files 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 and the Pathology Quality Manual is updated accordingly.

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 member’s personnel file (P: file) and the Trust induction records are also held by the 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/mentor and the training undertaken must be supervised and signed off by a senior member of staff before being classed as competent to perform the task. All staff are required to maintain their competencies specific to their job role and these competencies are specific to each department and the competency documents 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 (if applicable) 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 including mandatory training
- Competencies
- Evidence of individual actions that haven’t been actioned
- Issues that need to be discussed
- Agreed development plans
- Mandatory training
- CPD

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

The records of these PDRs are kept within the staff member's P: file.

All staff participates in CPD (there is currently a voluntary scheme provided by IBMS that most BMS staff 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 5.2.1-5.2.6)

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 including environment and facilities against regulatory standards
- Fire
- Anti-terrorism

All of these audits are stored on Q-Pulse in the audit module.

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 Care Group and the trust risk committee.

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 LL is responsible for:

- Maintaining a safe working environment for staff and visitors – this includes sites for primary sample collection
- Ensuring the working environment and facilities do not adversely affect sample integrity or quality of examinations, or the health and wellbeing of staff
- 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 LL is responsible for storage facilities and considers the following:

- Sufficient space
- Preservation and integrity of materials is maintained
- Security – 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:

- Principles of Procurement, including the relationship between Pathology and External Services [PA-QMS-PD-8]
- Principles of Equipment and Reagent Management [PA-QMS-PD-6]

These documents cover clauses 5.3.1.2-5.3.1.7 and 5.3.2 for key areas of equipment, reagent and consumable use, 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 SOPs.

All equipment involved in examination procedures are recorded 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 these are reviewed in the monthly CA/PA trending audit.

The Pathology Quality and Governance Manager 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 for ensuring the departmental equipment is maintained, calibrated and fit for use, and ensure 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.

5.29. Pre-examination processes (ISO Clause 5.4.1-5.4.7)

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 and on ICE (GP surgeries).

Request Forms

All request forms in Pathology are formatted to be compliant with ISO 15189 clause 5.4.3 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 and requesting has been tailored to individual surgeries requests wherever possible.

Consent for examination of the sample is taken from the signed request card by the requesting clinician.

Primary sample collection and handling and Pre collection and collection activities

Information is provided in the Pathology user guide [PA-GEN-MAN-2] which is available on the RCHT Intranet.

For all cancer screening programme samples, Section 251 prevents the need for consent to use patient information for national statistics and audit and this is covered by the RCHT Governance tool kit.

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. GPs and community hospitals are transported via Hospital couriers or Blood bikes.

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.

Freewheelers are a registered charity which offers out of hours, free of charge courier service to the NHS.

Information is provided in:

- Pathology user guide [PA-GEN-MAN-2]
Each department has detailed documentation for these transport of specimens 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 with consideration of the effect on the report
- Identification of urgent / priority samples
- Date and time when the sample is reviewed and by whom

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

The principles of handling and storage of specimens are described in Principles of Storage, Retention and Disposal of Clinical Material [PA-QMS-PD-14] in accordance with recommendations from the Royal College of Pathologists (Retention and storage of pathological records and specimens 5th edition), [PA-GEN-EX-6] 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]
- Joint Reception: [CH- AUTO-LI-2]
- CMB – Bacteriology: [CMB-BAC-LI-74]
- CMB – Virology: [CMB-VIR-LI-24]
- Haematology: [HA-GEN-LI-21]
- DMP: [DMP-GEN-SOP-5]

The departmental documents for retention of records include:-

- Blood Transfusion [BT-LI-38]
- Chemistry: [CH-GEN-LI-41]
- Joint Reception: [CH-GEN-LI-47]
- CMB – Bacteriology: [CMB-BAC-LI-68]
- CMB – Quality Records: [CMB-GEN-LI-21]
- CMB – Administration records: [CMB-GEN-LI-22]
- CMB – Virology: [CMB-VIR-LI-21]
- Haematology – Routine: [HA-AH-LI-29]
- Haematology – Coagulation: [HA-CO-LI-11]
- Haematology – Immunology: [HA-IMM-LI-11]
5.30. Examination processes (ISO Clause 5.5.1-5.5.3)

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

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

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-QMS-PD-12].

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

The MU is 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 5.6.1-5.6.4)

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 independent, relevant concentration third party internal quality control (IQC) with 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:

- Principles of Quality Control and Assurance [PA-QMS-PD-15]
- Principles of Internal Audit [PA-QMS-PD-16]

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. Poor performance letters are reported to the Pathology Quality and Governance Manager and then reported to the Pathology Quality and Governance meeting. Issues are escalated to weekly Care Group governance group by agreement with the LL.

Patient results are not released until IQC passes are obtained or risk management plans are documented and in place. When necessary, patient samples are reanalysed to ensure results are not erroneously requested.

**Interlaboratory comparisons**

The following document Principles of EQA [PA-QMS-PD-15], 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.

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 5.8.1-5.8.3 and 5.9.1-5.9.3)

Principles of Review, Report, and Release of Results SOP [PA-QMS-PD-13] describe the processes to be adopted by each department, which covers the following aspects:

- Report format
- Additional reports/supplementary reports/amended reports
- Staff able to authorise reports
- Interpretation and advice

The report released from each department covers the following –

- Identification of the examination
- Identification of the laboratory that issues the report
- Any examinations performed by a referral laboratory
- Patient identification and patient location
- Requester name and contact details
- Date of primary sample collection
- Type of primary sample
- Measurement procedure (where appropriate)
- Examination results
- Biological reference intervals
- Interpretation of results
- Other comments
- Any part of the examination that has been carried out as part of a research or development programme
- Identification of the person authorising the results
- Date and time of report
- Page number

The report content is audited by Pathology IT to ensure compliance to ISO 15189 and these audits can be found on Q-Pulse in the audit module.

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:

PA-QMS-PD-17 Principles of Laboratory Information Management

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 and these can be found on Q-Pulse.

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.

5.35. Trust Policies Relating to the Pathology Department

The Trust has developed a suite of documents which support the patients, hospital, departments and personnel at the RCH.

These policies are controlled and held by the trust, and are available for viewing and printing as required at the below detailed site which is part of the Cornwall & Isles of Scilly Intranet.


Some of these policies are also available on Q-Pulse for staff to read and acknowledge.
The below listed policies are relevant to the Pathology department. There are further policies which could be relevant to staff or certain situations which arise during the working day. These can be searched for and viewed by using the same internet address or on Q-Pulse as per detailed below.

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Q-Pulse Number (if applicable)</th>
<th>Aim of Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance Management Policy and Procedure (formerly Sickness Management Policy)</td>
<td>PA-GEN-GUIDE-9</td>
<td>Detail both the support that will be available to staff and the steps the Trust will take to monitor and manage attendance</td>
</tr>
<tr>
<td>Data Quality Policy</td>
<td>PA-GEN-EX-37</td>
<td>Set out a clear policy framework for maintaining and improving data quality within KCCG. The Data Quality Policy sets out how KCCG will collect, analyse and report data from the moment a patient or referral is received into the system to the point of discharge or death.</td>
</tr>
<tr>
<td>Risk Management and Management Strategy Policy</td>
<td></td>
<td>Ensures a consistent approach to risk management across NHS Kernow. Sets out the risk management framework which provides assurance to the Governing Body that robust and effective processes are in place to manage corporate and operational risks</td>
</tr>
<tr>
<td>Policy to Manage Information and Records</td>
<td></td>
<td>Sets out a framework within which the staff who use the Trust's clinical/health records can understand their responsibilities in line with specific policies and procedures which will ensure that records are managed and controlled effectively, commensurate with legal, clinical and operational information needs.</td>
</tr>
<tr>
<td>Policy on slips trips and falls prevention - Health and safety policy HSP 13</td>
<td></td>
<td>Describes the roles and responsibilities of trust personnel in relation to slips, trips and falls and looks at the preventative and control</td>
</tr>
<tr>
<td>Policy</td>
<td>Summary</td>
<td></td>
</tr>
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<td>----------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Information Governance Policy</td>
<td>It is of paramount importance to ensure that information is efficiently managed and that appropriate policies, procedures and management accountability and structures provide a robust governance framework for information management.</td>
<td></td>
</tr>
<tr>
<td>Equality and Diversity Policy</td>
<td>Provide staff within NHS Kernow with a framework to ensure that equality, diversity and human rights legislation is embedded within the organisation and to ensure that there are defined guidelines for patients, employees and visitors to follow.</td>
<td></td>
</tr>
<tr>
<td>On-call policy and procedure</td>
<td>Outlines the on-call operating principles which will apply to staff when on-call</td>
<td></td>
</tr>
<tr>
<td>Management of Violence and Aggression Policy (HSP19)</td>
<td>Defines policy, procedure, protocols for violence and aggression</td>
<td></td>
</tr>
<tr>
<td>Grievance and Disputes Policy and Procedure</td>
<td>The policy sets out the Trust's approach to managing grievances and disputes raised by staff.</td>
<td></td>
</tr>
<tr>
<td>Confidentiality Code for Employees Policy</td>
<td>Confidentiality Code for Employees Policy</td>
<td></td>
</tr>
<tr>
<td>Lone Working Policy</td>
<td>Defines policy, procedure and protocols for Lone Working</td>
<td></td>
</tr>
<tr>
<td>Security policy</td>
<td>Defines policy, procedure and protocols for security.</td>
<td></td>
</tr>
<tr>
<td>Health and Safety General Policy</td>
<td>To ensure the RCHT NHS Trust has in place a Health and Safety Policy that states the organisations commitment to staff, visitors, patients, contractors and all other persons affected by acts and omissions during the normal daily activities of the Trust.</td>
<td></td>
</tr>
<tr>
<td>Policy</td>
<td>Reference</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Annual Leave Policy</td>
<td></td>
<td>Provides a uniform and equitable approach to the management and calculation of annual leave and public holiday entitlement for NHS staff.</td>
</tr>
<tr>
<td>Equality Inclusion And Human Rights Policy</td>
<td></td>
<td>An over-arching reference policy that ensures equality, diversity and human rights is at the very core of the organization.</td>
</tr>
<tr>
<td>Hand Hygiene Policy</td>
<td>PA-HS-EX-38</td>
<td>Policy to highlight the importance of hand hygiene procedures in order to help reduce incidences of healthcare associated infections.</td>
</tr>
<tr>
<td>Smoke Free Policy</td>
<td></td>
<td>Aims to maintain a smoke free environment on Trust premises and assist staff, patients and visitors achieve improved health through smoking cessation.</td>
</tr>
<tr>
<td>IT Security Policy</td>
<td>PA-GEN-EX-38</td>
<td>Outlines the IT security policy, with guidance and directives for compliance.</td>
</tr>
<tr>
<td>Appraisal and Pay Progression Policy</td>
<td></td>
<td>This policy sets out the framework and process for conducting appraisals.</td>
</tr>
<tr>
<td>Incident and Serious Incident Policy</td>
<td></td>
<td>The document describes the policy and procedures for the reporting and management of incidents including Serious Incidents.</td>
</tr>
<tr>
<td>Sharps Safety Policy</td>
<td>PA-HS-POL-7</td>
<td>The purpose of this policy is to provide guidance to staff on safe practices when dealing with/using sharps.</td>
</tr>
<tr>
<td>Email Policy</td>
<td></td>
<td>Policy for managers, employees and CITS on the appropriate use of the email system.</td>
</tr>
<tr>
<td>Procurement Policy</td>
<td>PA-GEN-EX-51</td>
<td>To set out the legal and policy framework for all procurement undertaken by the Trust.</td>
</tr>
<tr>
<td>Stress Management - Policy for the Management of Work-Related Stress</td>
<td></td>
<td>This policy outlines the responsibilities of the Trust and its staff in recognising, managing and minimising stress at work and promoting.</td>
</tr>
<tr>
<td>Policy Type</td>
<td>Reference</td>
<td>Description</td>
</tr>
<tr>
<td>------------------------------------------------</td>
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</tr>
<tr>
<td>Disciplinary Policy and Procedure</td>
<td>PA-QMS-MAN-1</td>
<td>The policy provides managers and staff with a robust framework for managing any conduct issues or concerns that arise in a consistent manner across the Trust in line with current legislation and the ACAS Code of Practice.</td>
</tr>
<tr>
<td>Fire Safety Policy</td>
<td>PA-HS-POL-6</td>
<td>Outlines the Trust arrangements for the management of fire safety and arson prevention. Furthermore, to provide information on the practical management of Fire Safety within the Trust.</td>
</tr>
<tr>
<td>Air Tube Transport System Policy and Procedure</td>
<td>PA-GEN-EX-32</td>
<td>The Air Tube Transport System is used to transfer documents, specimens and medicines within the hospital.</td>
</tr>
<tr>
<td>Conflicts of Interest Policy</td>
<td>PA-GEN-EX-36</td>
<td>To highlight to all staff their potential exposure to breach of the Trust’s governance regulations, caused by offer of gifts and hospitality and through conflicts of interest.</td>
</tr>
<tr>
<td>Definitions of Harm</td>
<td>PA-GEN-EX-48</td>
<td>Describes the definitions of harm to use when completing a RCHT online incident form - Datix.</td>
</tr>
<tr>
<td>Personal file management policy</td>
<td>PA-GEN-EX-52</td>
<td>To provide a systematic approach to the management of personal files across RCHT.</td>
</tr>
<tr>
<td>Capacity Management escalation plan</td>
<td>PA-GEN-POL-6</td>
<td>Provides guidance for the whole Trust to manage a capacity or escalation event.</td>
</tr>
<tr>
<td>Decontamination Policy</td>
<td>PA-HS-POL-3</td>
<td>Provide information and guidance to all staff in relation</td>
</tr>
<tr>
<td>Major incident plan (MAJAX)</td>
<td>PA-HS-POL-8</td>
<td>Provides a structure for command and communication within the hospital, to ensure that the necessary action is taken to meet the needs of the incident.</td>
</tr>
<tr>
<td>---------------------------</td>
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<td>-----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Glove Use Policy</td>
<td>PA-HS-EX-35</td>
<td>Guidance to protect staff from the transmission of blood borne viruses and the prevention and reduction of adverse reactions to glove usage</td>
</tr>
</tbody>
</table>
APPENDIX 1 – TRUST BOARD STRUCTURE

Royal Cornwall Hospital Trust Board

Kate Shields
Chief Executive

Brian Courtney
Interim Company Secretary

Mairi McLean
Chairman

Susan Bracefield
Director of Operations

Kim O’Keeffe
Director of Nursing, Midwifery and Allied Health Professions

Sally May
Joint Director of Finance (RCHT/CFT)

Kelvyn Hipperson
Chief Information Officer

Thomas Lafferty
Director of Strategy and Performance

Kerry Eldridge
Director of HR & Organisational development

Allister Grant
Medical Director

Bernadette George
Interim Director of Integrated Governance

Non-Executive Directors
Paul Hobson
Sarah Pryce
John Lander
Dr Gillian Vivian
Ruth Allerton
Rob Leighfield
Margaret Schwartz

Royal Cornwall Hospitals NHS Trust
## APPENDIX 2 - CLINICAL STRUCTURE WITHIN ROYAL CORNWALL HOSPITAL TRUST (RCHT)

### General Surgery and Cancer Care Group
- Clinical Director: Bryson Pottinger
- General Manager: Charlotte Timmis
- Head of Nursing: Lorraine Sole (interim)

### Specialist Services and Surgery Care Group
- Clinical Director: Nick Wenger (interim)
- General Manager: Roz Davies
- Head of Nursing: Esther Penrose

### Clinical Support Care Group
- Clinical Director: Hannah Falvey
- General Manager: Richard Andrzejuk
- Allied Health Professionals: Emma Spouse (Interim)

### Women, Children and Sexual Health Care Group
- Joint Clinical Directors: Jon Clarke (interim), Tom Smith-Walker
- General Manager: Debra Shields
- Head of Nursing: Mary Baulch
- Head of Midwifery: Jane Urben

### Anaesthetics, Critical Care and Theatres Care Group
- Clinical Director: Awaiting candidate acceptance
- General Manager: Roberta Fuller
- Head of Nursing: Clare Blake (interim)

### Specialist Medicine Care Group
- Clinical Director: Awaiting candidate acceptance
- General Manager: Jo Floyd (Interim)
- Head of Nursing: Kate Schroder-Hockey (Interim)

### Emergency and Trauma Care Group
- Clinical Director: Mike Butler
- General Manager: Margaret Dalziel
- Head of Nursing: Vacancy

### Theatres
- Admissions
- Trelawney outpatients
- Urology
- Breast/Colorectal/Upper GI surgery

### Outpatients
- Paediatrics surgery
- General surgery
- Anticoagulant service
- Haematology
- Oncology
- Cancer wards

### Dermatology
- Rheumatology
- Oral and Maxillofacial Orthodontics
- ENT
- Audiology
- Ophthalmology

### Therapies
- Pharmacy
- Pathology
- Clinical Imaging
- Patient Services
- SSD
- Medical Physics
- Mermaid

### CLIC
- Paediatrics
- Paediatrics HDU
- Neonatal
- Maternity
- Gynaecology
- Community Therapies
- Midwifery

### Recovery
- ITU
- Critical Care
- Pain Services
- Anaesthetic Services
- Maternity Theatres

### Gastroenterology
- Endoscopy
- Alcohol Team
- Hepatology
- MDU
- Respiratory
- Psychology
- Neurology
- Endocrinology
- Diabetes
- Clinical Immunology
- Cardiology
- Nephrology

### Emergency medicine
- MAU
- Trauma
- Fracture clinic
- Urgent treatment
- Elder care
APPENDIX 3 - CLINICAL SUPPORT CARE GROUP STRUCTURE

Clinical Director
Hannah Falvey

General Manager
Richard Andrzejuk

AHP Lead
Emma Spouse (Interim)

Personal Assistant to General Manager/Clinical Director
Mandy Wemyss

Chief Pharmacist/Deputy AD
Iain Davidson

Pathology Services Manager/Deputy AD
Bruce Daniel

Business Administrator
Karen Etheridge

Care Group HR Business Manager
Nicole Steinkruger

Care Group Finance Manager
Tim Cockerill

Care Group Governance Facilitator
Kevin Wright

Service Improvement Lead
Sarah-Jane Davies

Chief Pharmacist/Deputy AD
Iain Davidson

Pathology Services Manager/Deputy AD
Bruce Daniel

Clinical Director
Hannah Falvey

General Manager
Richard Andrzejuk

AHP Lead
Emma Spouse (Interim)

Business Administrator
Karen Etheridge

Therapies
AHPT Lead
Clare Rotman

Urgent care Manager
Julieann Cockerton

Outpatient therapy manager
Maria Stickland

Pharmacy
AHPT Lead
Clare Rotman

Urgent care Manager
Julieann Cockerton

Outpatient therapy manager
Maria Stickland

Pathology
Speciality Director
Dr James Garvican

Pathology Service Manager
Bruce Daniel

Clinical Imaging
Speciality Director
Andrew Edwards

Imaging Lead
Emma Spouse

Radiography Service Lead
Jackie Knox

Patient Services
Head of Patient Services
Jayne Martin

Sterile Services Department
Operations Manager
Matthew Dyer

Production Manager
Jane Ham

Medical Physics
Speciality Director
Trevelyan Foy

Head of Clinical Technology
Matthew Bird

Head of Radiotherapy Physics
Savvas Rizkalla

Mermaid
Lead
Emma Spouse

Lead Consultant Director National Screening Programme
Dr Miklos Barta

Mermaid
Lead
Emma Spouse
APPENDIX 7 - CLINICAL CHEMISTRY DEPARTMENT STRUCTURE

CONSULTANT CLINICAL BIOCHEMIST / HOD
Band 8D
Dr Anthea Patterson

PRINCIPAL CLINICAL BIOCHEMIST
Band 8A
Anna Barton

SENIOR CLINICAL BIOCHEMIST
Band 7
Roxanne Farnon

HEALTHCARE SCIENCE PRACTITIONER
POCT / Referred Tests
Band 5
Kate Tregunna

SPECIALIST REGISTRAR IN METABOLIC MEDICINE
Dr Rachel Cooper

LABORATORY LEAD BMS
Band 8A
Lisa Vipond

BLOOD SCIENCES LEAD
Band 8B
Alain Rolli

SECTION LEAD
Point of Care Testing
Band 7
Helen Hobba

SECTION LEAD
Manual Band 7
Louise Simon

SECTION LEAD
Automation Band 7
Mowenna Sampson

H&S LEAD
Band 6 BMS
Alison Thornton

BIOMEDICAL SCIENTISTS (Band 5 & Band 6)
Fully rotational to cover 24/7 period

ASSOCIATE PRACTITIONER
Automated Laboratory x2

LABORATORY SUPPORT / JOINT RECEPTION STAFF
Band 2 MLSW and Band 3 MLA

QL
Band 6 BMS
Chantelle Pascoe

Indicates rotational posts
APPENDIX 8 - CMB DEPARTMENT STRUCTURE

CONSULTANT MEDICAL MICROBIOLOGIST/HOD
Dr Andree Evans

CONSULTANT MEDICAL MICROBIOLOGIST
Dr Kathy Bamford

LABORATORY LEAD CMB
Band 8a
Gemma Vanstone

A&C STAFF
Band 3
Band 2

LABORATORY ADMINISTRATOR
Band 5
Kathy Pollard

VIROLOGY LEAD
Band 8a
Herty Narcho

CLINICAL FELLOW

ANTENATAL SCREENING LEAD
Vacant * = Clinical Microbiologist
Team will cover post until position is filled

SENIOR BMS
Bacteriology/Quality
Band 7
Lindsey Vincent

SENIOR BMS
Bacteriology/IQA
Band 7
Vanessa Perks

SENIOR BMS
Bacteriology/Training
Band 7
John Lee

SENIOR BMS
Bacteriology/EQA, H&S
Band 7
Deborah Wadham

SENIOR BMS
Molecular/Virology
Band 7
James Griffiths

BMS
Band 5

BMS
Band 6

ASSOCIATE PRACTITIONER
Band 4

MLA
Band 3

MLSW
Band 2

Indicates rotational posts
APPENDIX 9 - DMP DEPARTMENT STRUCTURE

HOD/CONSULTANT PATHOLOGIST
SPECIALTY DIRECTOR
Dr James Garvican

DMP Lab Lead
Band 8b
Stephen Davison

Dissection
Lead BMS
Band 8a
Valerie Rodd

MCBU Senior
BMS Band 7
Mary Jones

Routine Senior
BMS Band 7
Georgina Purvis

Specials & IT
Senior BMS
Band 7
Matthew Coles

Diagnostic
Section Senior
BMS Band 7
Leonie Glinski

Rotational BMS
Band 6

Rotational BMS
Including Trainee
Band 5

Associate Practitioner
Band 4

MLA
Band 3

MLSW
Band 2

Pathologists
Dr Rob Jenkins
Dr Ilona Hopkins
Dr Juliane Stolte
Dr Rob Marshall
Dr Tom Grigor
Dr Hanne-Brit Smethurst
Dr Mihai Chifu
Dr Tim Bracey
Dr Katy Valentine

Administration
Manager Band 5
Natalie Blewett

Administration
Team Leader
Band 4

Administration
Secretary
Band 3

Administration
Clerk
Band 2

Mortuary Manager
Band 7
Kevin Hammett

Bereavement
Senior Band 5
Linda Warne

Bereavement
Officers
Band 4

Bereavement
Secretary
Band 3

Mortuary
APT
Band 4

Mortuary
Senior APT
Band 5

Mortuary / Bereavement
Trainee / APT Bereavement officer
Band 3

Indicates rotational posts