



PATHOLOGY QUALITY MANUAL

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26/04/2022	Added in the job description section that laboratory clinical leads have JDs on Q pulse GEN-MF-JDclinicallylead	VB
26/04/2022	The contract for gynaecological cytology is not commissioned by NWAFT to NNUH. The contract is an NHS E one and hence the information on page 6 and 11 can be removed as this service is not conducted on our behalf.	VB
26/04/2022	Microbiology currently runs the night shift service with no on-call BMS. I would suggest that section a) states that for urgent samples, the night shift BMS can be contacted via switchboard (as per the on call) and that section b) states that should a night shift not be possible, cover with be via on call.	VB
26/4/2022	HH Job title Band 4 staff are Associate Practitioner rather than BMA (Biomedical assistant)	VB
26/4/2022	Samba service added to HH section	VB

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26/04/2022

Bereavement Centre/Mortuary at Peterborough City Hospital operates 0800 - 1600

VB

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2 PURPOSE/SCOPE OF THE EXAMINATION

QUALITY MANUAL

This document, together with all related procedure manuals, represents the Quality Management System of the Department of Pathology, North West Anglia NHS Foundation Trust. The “Department of Pathology” describes the laboratories based at Peterborough City Hospital and Hinchingsbrooke Hospital and phlebotomy outpatient clinic at Stamford hospital. It has been compiled to meet the requirements of the 2012 revision of BS EN ISO 15189:2012 *Medical Laboratories – Requirements for quality and competence* and appropriate national and international standards. All procedures herein are mandatory within the Laboratories.

Purpose/Scope

This Quality Manual describes the Quality Management Systems (QMS) in use throughout the laboratories across the North West Anglia NHS Foundation Trust Hospitals. The QMS is the process developed to support the generation of an efficient and effective, high quality and appropriate laboratory advice, testing and recommendation service.

It encompasses all elements of quality delivery, including management systems, quality assurance and quality control.

The scope of the service provided by the Pathology Service is as follows:

An in-house routine diagnostic service for haematology, blood transfusion, biochemistry and microbiology based on the Peterborough City Hospital (PCH) site – these services are supplemented by a night shift running from 20.00 to 08.00 for the testing of urgent samples. Microbiology comprises – Bacteriology, virology/serology, mycology and parasitology.

An in-house routine diagnostic service for haematology, blood transfusion and biochemistry based on the Hinchingsbrooke Hospital site – these services are supplemented by a 24 hour out of hours shift system for the testing of urgent samples. Microbiology, Immunology and Histology for Hinchingsbrooke Hospital are currently provided at PCH.

An in-house routine diagnostic service for immunology is based at the PCH site. Monday-Friday 0800-1700

A routine in-house Cellular Pathology service is provided at PCH which includes histopathology and diagnostic non gynae cytology.

A bereavement service, body store and post-mortem suite based at PCH. The post-mortem service is available out of routine hours via an on-call system. Bereavement services and a body store based at Hinchingsbrooke Hospital also provides an on-call out of hours' system.

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A POCT service based at PCH covers POCT on both the PCH and the Hinchingsbrooke site.

Laboratory background

The Department of Pathology is part of the North West Anglia NHS Foundation Trust. As the legal entity North West Anglia NHS Foundation Trust can be held legally accountable for all of its laboratory and POCT activities.

On April 1st 2017 Peterborough and Stamford Hospitals NHS Foundation Trust, and Hinchingsbrooke Hospital Trust, merged to become North West Anglia NHS Foundation Trust.

It is primarily concerned with the analysis of clinical samples from the hospitals and the community. The hospitals served are Peterborough City Hospital, Stamford & Rutland Hospital and Hinchingsbrooke Hospital. Contracts are held for Pathology work from Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) and the local private hospital (Fitzwilliam Hospital). The community catchment currently includes parts of Cambridgeshire & Peterborough Clinical Commissioning Group (CCG), South Lincolnshire CCG, NHS Nene CCG and NHS East Leicestershire and Rutland CCG.

Other sources include HM Coroners, Ministry of Defence (MoD) establishments, Environmental Officers of Local Councils, HM Prisons, the Driver and Vehicle Licensing Authority and Aviation Accident Investigations. A variety of commercial contracts are held for food and environmental testing.

The contact details of the laboratory sites are:

Peterborough City Hospital
Edith Cavell Campus
Department of Pathology
Department 413
Bretton Gate
Peterborough
PE 3 9GZ
Tel: 01733 678468

Hinchingsbrooke Hospital
Department of Pathology
Hinchingsbrooke Park Road
Huntingdon
PE29 6NT
Tel: 01480 416151

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Mission statement

The Department of Pathology seeks to provide a high quality analytical, interpretive, and advisory and consultancy service that is cost-effective and responsive to the needs of our commissioners and patients.

It is committed to maintaining a safe working environment, a highly skilled workforce and utilising up to date technology to deliver the right result on the right specimen from the right patient that is accurate, properly interpreted and delivered within a clinically appropriate timescale.

The Pathology Management & Governance Committee (MGC) is dedicated to ensuring that this philosophy remains central to the practice of Clinical Pathology across North West Anglia NHS Foundation Trust.

Service scope

Service Scope BS EN ISO 15189:2012

Peterborough City Hospital Pathology department's scope of accreditation via BS EN ISO 15189:2012 can be found on the UKAS website:

Hinchingbrooke Hospital Pathology department has applied for BS EN ISO 15189:2012 accreditation.

Clinical Biochemistry

PCH:

The Department is divided into an Automated Section and a Separation Sciences section. Consultant Chemical Pathologists provide Clinical cover.

The Automated Section provides a diagnostic and therapy monitoring service 24 hours, weekdays, weekends and Public Holidays, using a variety of current techniques including ion specific electrodes, photometry and immunoassay (for endocrinology, tumour markers, vitamins, etc.). This section has duplicate analysis platforms to provide resilience for the service. This section is staffed throughout each 24-hour period.

The Separation Science section also oversees a range of techniques for diagnostic and monitoring assays including High Performance Liquid Chromatography (for HbA1c and urine aromatic amines) and electrophoresis. This section provides a full service during core hours, weekdays.

Hinchingbrooke:

Hinchingbrooke blood sciences biochemistry section also provides diagnostic and therapy monitoring services using state of the art technology for techniques as listed

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above but in a single section. The repertoire of test is not as extensive with some testing referred offsite. These tests are clearly outlined in the User Guide. A duplicate analysis platform and 24 hour staffing provides resilience for the section. Consultant Chemical Pathologists provide Clinical support.

Immunology

The Immunology Laboratory at Peterborough City Hospital offers a range of diagnostic, prognostic and monitoring tests in autoimmune serology. A broad array of allergy testing is available as well as investigation of latent tuberculosis. Tests required for suspected immune deficient patients are performed across a number of pathology disciplines including Immunology. Immunology requests from HH are performed at PCH.

A Consultant Immunologist provides supervision of the laboratory. Routine running of the laboratory is overseen by a Lead Scientist. More unusual immunology tests are forwarded to referral centres, which include Addenbrookes' Hospital in Cambridge and the Churchill Hospital, Oxford and Birmingham City Hospitals.

The Consultant Immunologist and lead scientist is available onsite to give clinical interpretation of results and to advise on which assays would be appropriate to request for different clinical situations, in particular co-ordinating and interpreting tests for immune deficiency some of which are not performed in Immunology (e.g. immunoglobulins and lymphocyte subsets).

Point of Care Testing

PCH and Hinchingsbrooke:

'Near-patient testing' (NPT) and 'Point-of Care testing' (POCT) are used synonymously to describe analytical procedures performed by healthcare professionals outside of the conventional laboratory. Operators performing the analysis must be appropriately trained and their competency recorded and monitored. The service must comply with those standards required for accreditation of the Pathology Department and adhere to the strict guidelines recommended by the Medicines and Healthcare Products Regulatory Agency (MHRA), and aims to comply with both BS EN ISO 15189:2012 and BS EN ISO 22870:2015 requirements

The Point of Care service currently oversees procedures performed using connected:

Blood glucose meters

INR meters

Blood gas analysers

Blood ketone estimation

Paediatric HbA1c analyser (PCH)

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POCT FBC analysers (in Haematology/Oncology Outpatient departments at PCH only)

Respiratory syncytial virus (RSV) screening test (PCH and HH only)

Urine strip readers (Hinchingsbrooke only)

Further developments will include, Urinalysis using connected devices and any POCT service approved by the POCT committee. Point of Care covers the Pathology disciplines of Clinical Biochemistry, Haematology and Microbiology, and operates Trust wide; wherever near patient testing is performed.

Point of Care testing also takes place at Stamford Hospital, however all Clinical Biochemistry, Haematology, Blood Transfusion and Microbiology routine samples are processed at the PCH laboratory.

More information can be found in the POCT Policy (POCT-TRUST-POCT Policy)

Haematology and Blood Transfusion

PCH:

The Department of Haematology includes Routine & Specialised Haematology, Coagulation and Blood Transfusion sections.

A number of Consultant Haematologists provide clinical cover.

Dr Sateesh Nagumantry is the clinical lead for the ANNBS programme for SCT.

The Haematology section provides a diagnostic & monitoring analytical service of malignant and non-malignant blood disorders using state of the art technology & computer software. Included here is detection & identification of parasitic infections.

The Specialised Haematology section includes flow cytometry-based leukaemia / lymphoma diagnosis and leucocyte subset analysis in immunodeficiency syndromes.

The Coagulation section uses similar levels of technology but the aims are screening, diagnosis of coagulation defects including coagulopathies, providing qualitative as well as quantitative information as well as monitoring patients on short & long-term anticoagulant therapy. This section provides testing for the Trust's anticoagulant service.

The Blood Transfusion section also utilises state of the art technology & software and has been a leader in the field of modern practice. Services provided are compatible blood and blood components, as and when required making the most efficient use of a valuable and limited resource. It also provides a serological antenatal service to the community including monitoring of prophylactic anti D and diagnostic service for the investigation of haemolytic disease.

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Hinchingbrooke:

On the Hinchingbrooke site General Haematology and Coagulation is provided to support the clinical areas using modern analysers and techniques. Routine diagnostic and monitoring services are supplemented by specialist service referrals to PCH.

Transfusion services are provided at Hinchingbrooke Hospital to support the clinical areas and the community antenatal team. High level technology allows the safe provision of blood and blood components and the issue of blood products.

Medical cover is provided by the NWAFT Consultant Haematologists on a rotational basis.

Cellular Pathology & Bereavement Services**PCH:**

The Cellular Pathology department includes Histopathology and Diagnostic Non-Gynae Cytology. Histopathology provides a service for the clinical diagnosis of disease from human tissue samples.

The Diagnostic non-gynae Cytology service provides clinical diagnosis of disease from aspirated or expelled fluid samples.

A number of Consultant Histopathologists provide clinical cover for the Cellular Pathology Service.

The Bereavement Centre offers support to the family of deceased patients. The Mortuary provides a service for the receipt and storage of deceased patients prior to funeral and the assessment of cause of death to meet statutory requirements or for purposes of teaching and clinical audit.

Hinchingbrooke:

Histology services for the Hinchingbrooke site are provided on the PCH site.

At Hinchingbrooke, bereavement and body store services are also provided, offering support to families and assistance to the local funeral directors.

Microbiology**PCH:**

The Microbiology department provides a Clinical microbiological diagnostic service to the Clinical Divisions (CDs) of the Trust and its associated general practitioner community. The Laboratory is a designated UKHSA Collaborating Centre.

Clinical input is provided from the Consultant Clinical Microbiologists.

Comprehensive microbiological and epidemiological information and support is available to consultants in Communicable Disease Control and their colleagues in Public Health Medicine.

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Local surveillance and special studies in infectious disease are undertaken.

Microbiological support for the Control of Infection function is provided.

Investigation and support in community and national outbreaks of communicable disease is available when required.

Hinchingbrooke:

The Microbiology service for Hinchingbrooke Hospital is provided by PCH. Clinical support is available from the NWAFT Consultant Clinical Microbiologists.

A rapid testing service for Covid 19 is provided at the Hinchingbrooke site using the Samba service with PCR confirmation testing provided at PCH.

Phlebotomy

The Sarstedt Monovette blood collection system is in use throughout the Trust.

PCH:

Venous blood sampling is an integral part of the diagnostic process that facilitates appropriate treatment and patient care. It is essential that samples of high quality are taken with minimum discomfort to the patient. It is also vital to minimise the risk of cross - infection between patients.

An inpatient service is provided at PCH Monday to Friday 0800–1200 and a limited service provided at weekends and bank holidays by a team of skilled phlebotomists, who are reassessed and competencies are checked at a maximum of two years.

All request forms should be made available for collection each day at 0800 in the relevant ward areas. The phlebotomists take routine bloods only. Emergency bloods should be taken by the ward medical staff.

Hinchingbrooke:

At Hinchingbrooke Hospital an inpatient phlebotomy service is provided between 08:00 and 12:00 each weekday, and between 07:00 and 11:00 on Saturday, Sunday and Bank Holidays mornings. A corresponding outpatient service is provided from 09:00 - 17:00 on weekdays only. This service is provided from Hinchingbrooke's Treatment Centre.

Inpatient requests **must** be left at the appropriate nursing station by 07:30 weekday and 06:30 weekends/ bank holidays to be collected when the phlebotomists call. Phlebotomists will visit each ward once daily. At weekends and Bank Holidays a limited service is provided (generally only two phlebotomists are on duty on these occasions) and it is expected that workloads will be restricted to essential investigations only.

Stamford:

A phlebotomy service at Stamford is available Monday to Friday from 0830 to 1700 hours for outpatients and for GP's from 0830-1630 hours.

Phlebotomy staff across the Trust are managed by the Phlebotomy Manager cross site working.

Referral of Specimens

The Pathology Service is supported by referring work to specialist centres.

Full details are given in Appendix 4 (Referral Centres) of this quality manual.

Service Guides**PCH:**

The Pathology User guide for PCH is the Pathology website: www.pch-pathlab.com. This website can be reached via the Trust Intranet (internal users) and Extranet (external users e.g. General Practitioners and staff).

Hinchingbrooke:

The Pathology User guide for Hinchingbrooke is also accessible via the PCH pathology website, by following the links for "Hinchingbrooke". The direct link is: www.pch-pathlab.com.

Opening Hours**PCH:**

Core hours of the Department of Pathology are 9am to 5 pm Monday to Friday, but each department has extensions to reflect service need. Microbiology is open 08.00-20.00 Monday to Friday.

An out of hours' system for haematology, blood transfusion and clinical biochemistry, and an on call service for microbiology, provides cover outside of routine hours.

Bereavement Centre / Mortuary:

The Bereavement Centre and Mortuary at Peterborough City Hospital operates from 0800 to 1600 Monday to Friday. There is an on call facility that provides a mortuary service outside of these hours.

POCT:

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The POCT service routine operating hours are 0800 to 1600 hours.

Hinchingsbrooke Hospital:

Core hours are 9am to 5pm Monday to Friday with extra support for the out of hours shift service 8am-9am and 5pm-8.45pm.

The out of hours shift service covers from 8.45pm – 08:45am weekdays and 24hrs over weekends and bank holidays.

Out of Hours cover Arrangements

PCH:

Clinical Chemistry

The Department of Clinical Biochemistry offers an out of hours service to service users.

Staff

Participation in this service is undertaken by HCPC Registered Biomedical Scientists (BMS), is contractual and is available to any BMS competent within the discipline, provided the first criterion is met.

Hours of Service

The normal (in hours) day is taken as Monday to Friday inclusive, from 0800 – 1630 with an extended service until 2000 from February 2010.

Duties outside of these times are considered out of hours.

Repertoire

The assays available to service users' out-of-hours tend to be all general routine biochemistry analytes that are available on routine analytical platforms. However, this list is not exhaustive and is subject to change. If staff are unsure, then they would seek advice from senior Biochemistry staff (usually Consultant Chemical Pathologist or Head BMS)

The following analyses are available without recourse to Clinical/Senior staff: sodium, potassium, chloride, creatinine (U/E); CO₂; urea; albumin; total bilirubin; alkaline phosphatase; ALT; total protein (LFT); calcium; inorganic phosphate; amylase; uric acid; glucose; troponin T; CPK; CRP; direct bilirubin; magnesium; paracetamol; salicylate; lipids; and lactate.

The following assays are available but the laboratory should be contacted and made aware of the request: ammonia; iron (in cases of suspected toxicity); plasma osmolality; urine osmolality; phenytoin; lithium; digoxin; theophylline, pregnancy test; urine porphobilinogen.

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Also available at weekends are: progesterone; hCG (to 13:00); gentamicin and vancomycin (both to 13:00; other requests via the Consultant Microbiologist).

Requests received out of hours for process during out of hours should be marked either URGENT or EMERGENCY.

The service is available to all wards at PCH and Stamford, the Fitzwilliam Hospital and on occasions to GP/Rapid Response teams (usually agreed with duty BMS directly)

The emphasis should be on providing a service to users, making access easy and offering a fast turnaround of results, maintaining high quality.

For work that cannot wait for these programmed run times, the requester will bleep the duty BMS and give advice on the request. All emergency requests should also bleep duty BMS – this includes all ammonia and lactate requests.

Immunology

The normal (in hours) day is taken as Monday to Friday inclusive, from 0800 – 1630.

Few tests performed by the department are required clinically on an urgent out-of-hours basis.

Haematology and Blood Transfusion

Staff

Participation in this service is undertaken by HCPC Registered Biomedical Scientists (BMS), is voluntary and is available to any BMS competent within the discipline, provided the first criterion is met.

Hours of Service

The normal (in hours) day is taken as Monday to Friday inclusive, from 0800 – 1630 with an extended service until 2000.

Duties outside of these times are considered out of hours.

Staff requesting on call tests MUST bleep the on-call Haematology BMS via bleep 1151 or switchboard for:

- ALL requests for blood & blood products.
- If the diagnosis is query Malaria.
- If the results have not appeared on the ward terminal when required.

Microbiology

Out of hours service for essential and urgent work by its very nature is almost always hospital based clinical bacteriology, but the service is available to others e.g. GPs and Environmental Health Departments if urgently needed.

a) Essential Microbiology Service.

Such work is carried out 7 days a week 0845 – 1700 with an extension up until 2000 Monday to Friday by an HCPC Registered Biomedical Scientist (BMS) attending the department. Reading and reporting of culture plates is the prime function with no service offered, for example, for routine Serology or Virology. Significant positive results on important specimen (e.g. blood culture, C.S.F. etc.) will be telephoned before the BMS leaves the department.

Currently microbiology operates a night shift 20:00-08:00. For urgent samples and for SARS-CoV-2 testing, the night shift BMS can be contacted via switchboard (as per the on call)

b) Urgent Microbiology Service.

This service operates at all other times than those mentioned above, by calling the Biomedical Scientist (BMS) on-call to attend from their home base. Use of the service should be restricted to genuine emergencies only. Should a night shift not be possible, cover will be via on call.

The emergency duty roster is held at PCH main switchboard (Tel: 01733-678000) through whom the duty BMS can be contacted. A mobile phone and a radio-pager are available for use at the convenience of the BMS On-Call.

c) Medical Advice.

Medical advice is available out of hours from a Consultant Medical Microbiologist who is also contactable via PCH main switchboard (Tel: 01733-678000). A mobile phone and radio-pager are carried.

d) IDIPS.

Dr Dennis Mlangeni is clinically responsible for the Infectious Diseases in pregnancy screening programme. (IDIPS)

Cellular Pathology

There are no formal arrangements for processing samples out of hours although this may be possible in cases of urgent clinical need where the case has been discussed with a Consultant Histopathologist and they have given permission for urgent processing to take place.

Mortuary

An on call service is available which covers outside of normal working hours.

Hinchingbrooke:

Blood Sciences

Blood Sciences at Hinchingbrooke Hospital offers an out of hours shift service covered by HCPC Registered Biomedical Scientists (BMS) and Associate Practitioner (AP) staff.

Repertoire

Biochemistry

The following analyses are available without recourse to Clinical/Senior staff: sodium, potassium, creatinine (U/E); urea; albumin; total bilirubin; alkaline phosphatase; ALT; total protein (LFT); calcium; inorganic phosphate; amylase; uric acid; glucose; troponin T; CPK; CRP; direct bilirubin; magnesium; paracetamol; salicylate; lipids; Iron studies; osmolality(serum and urine); digoxin; theophylline; hCG; gentamicin and vancomycin

The following assays are available but the laboratory should be contacted and made aware of the request: ammonia; thyroid function (if required urgently)

The service is available to all wards, offering a fast turnaround of results and telephone support. Bleep for urgent request no 1150.

Clinical support is provided by Consultant Chemical Pathologists.

Haematology / Coagulation / Transfusion

Routine testing is offered via request forms with emergency work accompanied by a bleep to alert staff if required. Bleep no 1257. Emergency blood and blood component requirements must always be discussed with the duty BMS. Specialist coagulation testing must be cleared with the On-Call consultant haematologist, who is also available to support massive blood loss situations offering guidance for component and product requirements.

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Organization and management responsibility

Organization

Peterborough & Stamford Hospitals NHS Foundation Trust merged with Hinchingsbrooke in 2017 to become North West Anglia NHS Foundation Trust. North West Anglia NHS Foundation Trust is assessed for regulatory compliance against the Act by both Monitor and CQC. Monitor licence number 120083

The Pathology Laboratories at Peterborough and Hinchingsbrooke are a part of North West Anglia NHS Foundation Trust's FISS (Family and integrated Support Services) division.

Ethical Conduct (4.1.1.3) –

Via the Pathology MGC laboratory management ensures that there is no involvement in any activities that could diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity.

All of the activities undertaken are free from any undue commercial, financial, or other pressures and influences that could adversely affect the quality of work produced.

Should competing interests exist – MGC requires that staff openly declare these via completion of a *register of interests* form in compliance with the Trust's *Policy on Business Conduct and Bribery Avoidance* and *Managing Conflicts of interest Policy* (available on the Trust Intranet).

All staff are aware of the need to formally raise concerns when they encounter or suspect wrong doing or malpractice and it would be in the public interest for these concerns to be raised. The Trust Policy 'Raising Concerns in a Safe Environment' outlines the process to be followed and quotes examples of when this may apply.

These include:

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

All staff are aware of the requirement to ensure that all samples are dealt with in accordance with UK legal requirements including compliance with environmental and waste regulations.

All staff are aware of the need to ensure that confidentiality of information is maintained at all times in accordance with the Trust's *Data Protection and*

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Confidentiality, and Information Governance Policies (available on the Trust Intranet).

Each year, all staff members have an annual MPA (My Performance Appraisal) The performance appraisal documents checklist reviews if the staff member need to make a conflict of interest declaration.

Laboratory Director –

The Laboratory Director is Dr David Bailey who is the Pathology Associate Clinical Director (ACD) and is a Consultant Histopathologist. Dr Bailey is accountable to the Clinical Director who together with the Directorate General Manager have executive accountability for the service via the Trust's Chief Operating Officer as shown on the organisation chart below.

For full details of the laboratory director's role and responsibilities please see the associated *Laboratory Director* document (ref: GEN-QP-LabDirector) which is available via Q-Pulse.

Organisational structures can be found in Appendix 1 (GEN-QP-0001D Organisational Charts)

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Management Responsibility

Management Commitment

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

Ensuring that all laboratory personnel are aware of and comply with regulatory and accreditation requirements.

Ensuring that all laboratory personnel are aware of and comply with the needs and requirements of service users.

Establishment of the departmental Quality Policy (see below).

Ensuring that quality objectives and plans to achieve these objectives are in place.

Defining the responsibilities, authorities and interrelationships of all personnel (see QM Appendix 1 – available via Q-Pulse).

Establishment of effective communication processes with staff and also with the service stakeholders.

Establishment of, and appointment to, the role of Pathology Quality Manager (PQM).

Ensuring that management quality reviews occur on at least an annual basis.

Ensuring that staff are competency assessed to provide assurance that they are competent to perform their assigned activities.

Ensuring that there are adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities.

Needs of Users

Laboratory management regularly reviews the service provided to ensure that it meets the needs of service users and the patient population served.

Direct meetings are held with commissioners where feedback is provided, issues are discussed and any required actions agreed. In addition, hospital clinicians provide feedback via formal clinical ward rounds and during Multi-Disciplinary Team (MDT) meetings.

Complaints received from users are fully investigated and any necessary corrective actions undertaken.

Assessment of user satisfaction and complaints is conducted on an annual basis and consideration of the findings form part of the annual management review.

Communication of changes to users of the service is also via the website and Connect information paper for internal users of the service.

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Quality Policy

Department of Pathology management has defined the following Quality Policy which meets the requirements of this International Standard and is appropriate to the purpose of this organization.

The Quality Policy can additionally be found as an independent document; Q-Pulse (GEN-QP-0001A)

The Pathology Service is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users.

In order to ensure that the needs and requirements of users are met, the Department will:

- operate a quality management system to integrate the organisation, procedures, processes and resources.
- set and review quality objectives and plans in order to implement this quality policy.
- ensure that all personnel are familiar with this quality policy to ensure user satisfaction.
- ensure that all personnel are familiar with the contents of the quality manual and all procedures relevant to their work.
- uphold professional values and be committed to good professional practice and conduct.
- commit to the health, safety and welfare of all its staff.
- ensure that visitors to the department will be treated with respect and due consideration will be given to their safety while on site.
- keep advised of and implement, where applicable, all current legislation relating to the Health and Safety of staff and visitors.
- comply with relevant environmental legislation.
- conform to confidentiality in accordance with The Data Protection Act, NHS Information Governance and Caldicott Guidelines.

The Department will continue to comply with standards set by BS EN ISO 15189:2012, BS EN ISO 22870:2015 and assessed by UKAS, The Blood Safety and Quality Regulations and The Human Tissue Authority and is committed to:

- staff recruitment, training, development and retention at all levels to provide a full and effective service to its users.
- the proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service.
- the collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations.

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- the use of examination procedures that will ensure the highest achievable quality of all tests performed.
- reporting results of examinations in ways which are timely, confidential, accurate and clinically useful.
- the assessment of user satisfaction, in addition to internal audit, external quality assessment, identification and control of nonconformities in order to produce continual quality improvement.

Signed on behalf of the Department of Pathology

.....**Date**.....

(N.B signed copy held as separate document).

Chair Pathology Management & Governance Committee (MGC)

This Quality Policy is reviewed at least annually as part of the Management Review process.

Quality Objectives and Planning

The Trust decides upon its strategic objectives on an annual or biennial basis. Objectives for the pathology department, which link to these are then agreed by Pathology MGC. The laboratory Quality Forums (QF) have latitude to create their own specific departmental objectives as long as they clearly link to the pathology objectives.

The management review that is undertaken on an annual basis, and monitored quarterly, determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans, and the functioning of the QMS. Reports are available on Q-pulse.

Responsibility, authority and interrelationships

Organisation Charts for Pathology can be found as an appendix of this quality manual (Appendix 1) which is available via the Documents Module of Q-Pulse. This details:

- Trust Management Structure
- Pathology Reporting Responsibilities
- Clinical Management Structure
- Technical Management Structure
- Quality Management Structure
- Hinchingsbrooke Structure
- Clinical Biochemistry & Immunology Structure

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- Haematology and Blood Transfusion Structure
- Cellular Pathology Structure
- Microbiology Structure
- POCT structure

In addition, the names and roles of senior laboratory staff are contained within an appendix of this Quality Manual (Appendix 2) which can be accessed via the Documents Module of Q-Pulse.

Non-medical staff are accountable to the Pathology Services Manager (PSM) Matt Smith through the Departmental Manager. Clinical scientist staff are accountable to the clinical head of department for clinical issues and managerially accountable to the PSM through the Departmental Manager.

Pathology medical staff are accountable directly to the Directorate Associate Clinical Director (ACD).

Departmental Quality Officers (QO's) are responsible through their Departmental Manager to the Pathology Quality Manager (PQM) for issues relating to quality and the maintenance of the QMS.

Departmental H&S Officers are responsible through their Departmental Manager to the PSM who has ultimate responsibility for ensuring the Health, Safety and Welfare of staff and visitors within Pathology.

Departmental Training Officers are responsible through their Departmental Manager to the PSM who has ultimate responsibility for ensuring compliance with National and Trust training requirements.

It is a policy of the laboratory that all senior Biomedical Science staff must have proven technical and managerial competencies appropriate to the post held. They must be Registered with the HCPC and have relevant qualifications such as Licentiate, Member or Fellowship of the Institute of Biomedical Sciences (IBMS) or be HCPC registered Clinical Scientists.

Registered Medical, Biomedical Scientists and Clinical Scientists are authorised signatories for clinical reports within their specialist areas of competence:

In the absence of key managerial staff, the appropriate appointed deputy fulfils the role of the absent member of staff.

All staff are issued with a job description detailing the general extent and limitations of their responsibilities. These are reviewed annually at *My Performance Appraisal* (MPA) meetings for laboratory and clerical staff and at appraisals for medical staff.

On a day-to-day basis, specific duties relating to these responsibilities are discharged through the member of staff with direct responsibility for the supervision of any given individual.

- It is the responsibility of all employees to become familiar with and participate in Quality Management and the requirements of the Pathology QMS.

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- Staff must at all times follow documented and approved SOPs.
- Staff must become familiar with the contents of this Laboratory Quality Manual.
- Staff must complete a Trust Datix adverse event record and a Corrective Action / Preventative Action (CA/PA) record on Q-Pulse as soon as a nonconformity is identified in order that prompt and appropriate action can be taken to control the problem.
- Staff must participate in annual appraisal.
- BMS staff must record self-assessments and Continuing Professional Development (CPD) activities within their personal portfolios and ensure that their competency records are kept up to date.

This document forms part of the laboratory documentation. It is an overview of quality and should be read in conjunction with other documentation:

Trust Policies are available via the Trust intranet;

Pathology Diagnostic Policy

POCT Polices

Mortuary Policies

Q-pulse:

Laboratory Quality Policies

Quality Audit Manual (GEN-QP-AUDMAN)

Evaluation & Quality Assurance (GEN-QP-EVALQA)

Quality Improvement (GEN-QP-QIMPROVEMENT)

Education Support Policy (GEN-TRN-POLICY)

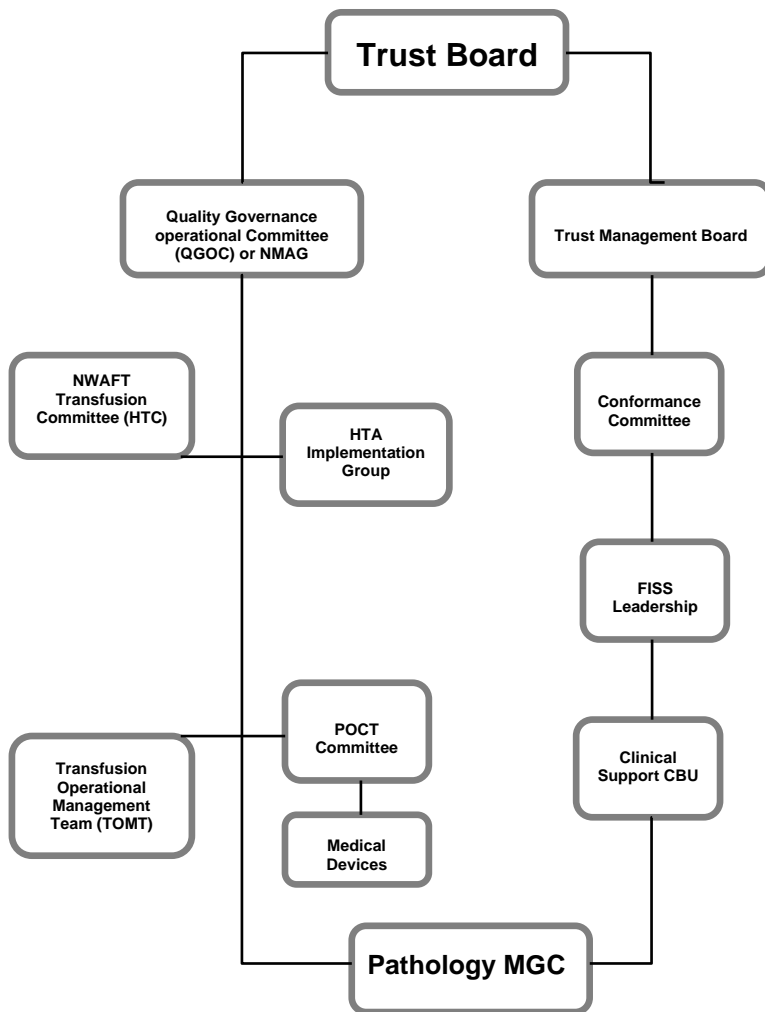
Communication

Staff meetings occur in laboratory areas and active participation by all staff is encouraged. These meetings also offer opportunities for staff to suggest changes and quality improvements. Minutes of the meetings are taken, recorded on Q-Pulse and distributed electronically to the staff via Q-Pulse.

A number of management meetings occur to ensure that there is suitable dialogue between pathology and Trust management as shown here:

See document GEN-EXT-FISSGOVSTRUC for the FISS division's meeting structure.

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Pan-Pathology				
Meeting	Frequency	Aims refer to:	Minutes recorded	Feeds into
MGC	Monthly	GEN-TOR-MGC	Q-Pulse	Division level meetings
Quality Forum (NWAFT))	Monthly	GEN-TOR-QualityForum	Q-Pulse	MGC, Departmental meetings

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IT Forum	Monthly	GEN-TOR-IT	Q-Pulse	MGC, Departmental meetings
H&S Forum (NWAFT))	Bi-Monthly	GEN-TOR-H&SCommittee	Q-Pulse	MGC, Departmental meetings
POCT Forum	3 Monthly	GEN-TOR-POCT	Q-Pulse	MGC, Departmental meetings, Medical devices
Education, Learning & Development Forum	Monthly	GEN-TOR-Ed&Dev	Q-Pulse	MGC, Departmental meetings
AMR annual (NWAFT)	Yearly	Review of departmental performance, achievements, issues, developments and objectives.	Q-Pulse	MGC, Departmental meetings

Departmental- Senior team meetings

Clinical chemistry DMT	Monthly	GEN-QF- DeptMeetingTemp	Q-Pulse	Depending on issue-MGC, Training, Quality, H&S, HR or IT
Haematology /Transfusion senior meeting	Monthly	GEN-QF- DeptMeetingTemp	Q-Pulse	Depending on issue-MGC, Training, Quality, H&S, HR or IT
Microbiology Senate meeting	Monthly	GEN-QF- DeptMeetingTemp	Q-Pulse	Depending on issue-MGC, Training, Quality, H&S, HR or IT
Cellular Pathology Governance meeting	Monthly	GEN-QF- DeptMeetingTemp	Q-Pulse	Depending on issue-MGC, Training, Quality, H&S, HR or IT
Cellular Pathology senior meeting	Monthly	GEN-QF- DeptMeetingTemp	Q-Pulse	Departmental senior meeting

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Departmental meetings				
Clinical Chemistry	Monthly	BIO-QF-DeptAgenda	Q-Pulse	Departmental senior meeting
Haematology /Transfusion	Monthly	HAE-QF-DeptAgenda	Q-Pulse	Departmental senior meeting
Microbiology	Weekly	MIC-QF-SeniorAgenda	Q-Pulse	Departmental senior meeting
POCT meeting	Monthly	POCT-QF-DeptAgenda	Q-Pulse	Departmental meeting
Cellular Pathology	Monthly	CP-QF-DeptAgenda	Q-Pulse	Departmental meeting
Specimen Reception	Monthly	SR-QF-DeptAgenda	Q-Pulse	Departmental meeting
Phlebotomy (Stamford, PCH and HH)	Monthly	Phleb-QF- DeptAgenda	Q-Pulse	Departmental meeting
Microbiology	Weekly, then monthly with clinical staff	Mic- QF-DeptAgenda	Q-Pulse	Departmental meeting
Mortuary and bereavement	Monthly	MOR- QF-DeptAgenda	Q-Pulse	Departmental meeting
Haematology /Transfusion	Monthly	HAE-QF-DeptAgenda	Q-Pulse	Departmental meeting
Immunology & Biochemistry	Monthly	GEN-QF-DeptMeetingTemp	Q-Pulse	Departmental meeting

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Immunology clinical meeting	Monthly	GEN-QF-DeptMeetingTemp	Q-Pulse	Departmental meeting
Super TOMT (NWAFT)	Fortnightly	GEN-TOR-TOMT	Q-Pulse	MGC, HTC
TOMT	Fortnightly		Q-Pulse	MGC, HTC

In addition, there are regular opportunities for service user feedback on the effectiveness of the laboratory's service via dedicated commissioner meetings, formal clinical rounds, MDT participation and via periodic service user feedback surveys. This includes the Antenatal screening steering group and the North West Anglia Antenatal and New-born screening programme board.

The main management committees within the Pathology service together with their remits are listed within appendix 3 of this Quality Manual (available via Q-Pulse).

Terms of reference exist for these meetings. Minutes of these meetings are held with specific action points noted and assigned to specific staff together with an agreed timescale for implementation.

Quality Manager

A Pathology Quality Manager (PQM) has been appointed who is a member of the Pathology Management & Governance Committee and who ensures on behalf of MGC that the Quality Management System functions effectively. The PQM's job description is available via Q-Pulse.

The Pathology Quality Manager also has a deputy quality manager cross site to provide support and continuity, when required.

Quality management system (QMS)

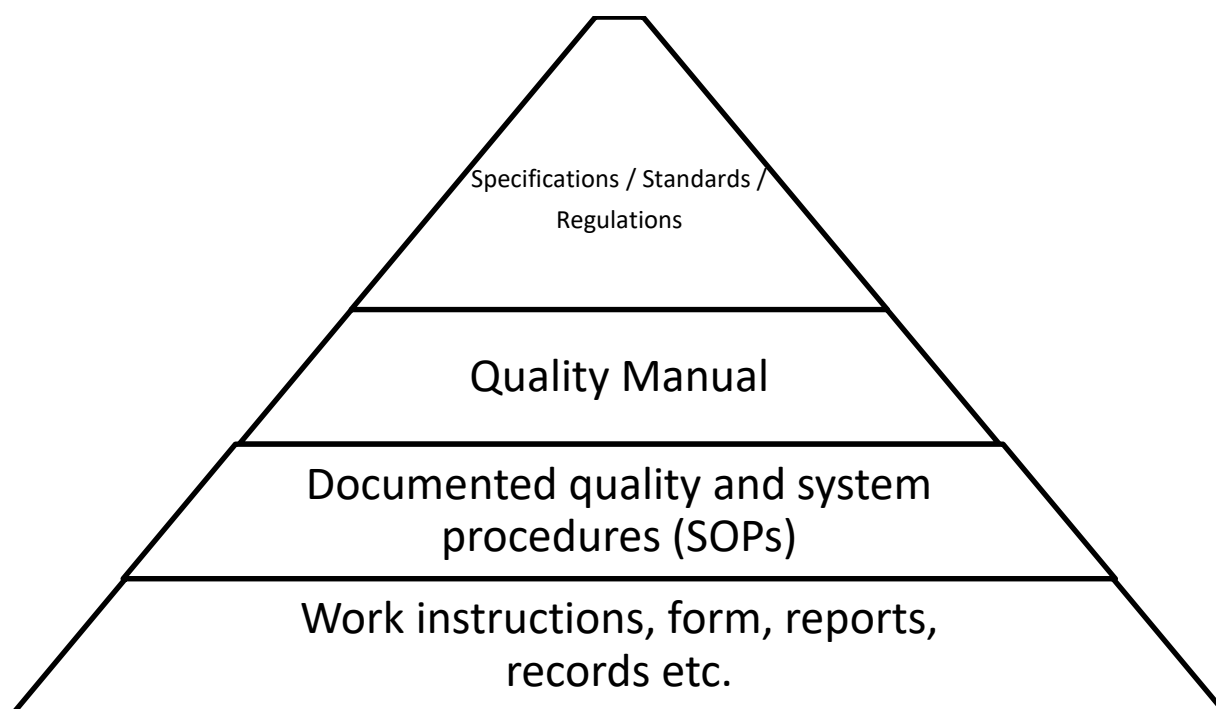
General requirements

Through the creation of this quality manual laboratory management has provided documentary evidence of the existence of a QMS. Laboratory management will endeavour to improve the effectiveness of this QMS in accordance with the requirements of International Standard BS EN ISO 15189:2012.

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Documentation requirements

Hierarchy of the documentation system is shown below:



This Quality Manual defines and describes the Quality Management Systems in use at NWAFT. It references the department's Quality Policy which contains a statement of our aspirations with regard to quality.

This Quality Manual outlines the general form of the Quality Systems in operation in the Department of Pathology at each site, identifying the general arrangements for ensuring that the quality policy is adhered to by staff at all times. It describes the Quality Management Systems for the benefit of laboratory management and staff and provides information for users and for inspection/accreditation bodies.

The sections of the Quality Manual are arranged so that they equate with the BS EN ISO 15189:2012 Standard. Under each of the standards is a brief description of the way in which the Department of Pathology seeks to comply with the particular standard and references are given to appropriate procedures.

More detailed procedures pertaining to the implementation of the quality management system in different parts of the laboratory can be found in the following manuals:

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- Quality Audit Manual¹ (GEN-QP-AudMan)
- Pathology Education Support Policy¹ (GEN-TRN-Policy)
- Quality Improvement¹ (GEN-QP-QImprovement)
- Evaluation & Quality Assurance¹ (GEN-QP-EvalQA)
- Laboratory Health and Safety Manual¹ (Q-pulse: HS-H&S-Manual,)
- Trust Procedures and Policies²
- Trust Risk Management & Risk Assessment Policy²
- Trust Health & Safety Policy²

Departmental SOP Manuals

Hinchingbrooke Hospital

Blood Sciences: Biochemistry

Instrument Standard Operating Procedures Folder

Analytes Standard Operating Procedures Folder

General Biochemistry Standard Operating Procedures Folder

Blood Sciences: Haematology

Coagulation Analyser Standard Operating Procedures Folder

¹ Available via Q-Pulse

² Available via the Intranet on SharePoint

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XN 9100 Standard Operating Procedures Folder

General Haematology Standard Operating Procedures Folder

Transfusion:

Technical Standard Operating Procedures Folder

Non-Technical Standard Operating Procedures Folder

Reception:

Reception Standard Operating Procedures Folder

General Standard Operating Procedures Folder

Other:

Bereavement Centre / Mortuary Standard Operating Procedures Folder

Phlebotomy Standard Operating Procedures / Policy Folder

Peterborough City Hospital

Clinical Biochemistry:

Methods Manual

Instrument Manuals

Administration Manuals

Laboratory IT Manual

Specimen Handling

Haematology and Blood Transfusion:

General Haematology Manual

Coagulation Manual

Blood Transfusion Manual

Immunology:

Equipment Manuals

ELISA assays

Immunofluorescence

Allergy assays

Laboratory Support Manual

Cellular Pathology

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Clinical procedures Manual
Management procedures Manual
Laboratory procedure Manuals for:
 Histopathology
 Diagnostic Non-gynae cytology
 General laboratory areas.

IT procedures Manual
Quality procedures Manual
Office administration Manual
Bereavement Centre / Mortuary procedure Manuals

Microbiology

Clinical Bacteriology Manual
Blood Culture Manual
Mycology Manual
Enteric Section Methods Manual
Urine Section Methods Manual
Serology / Virology Section Methods Manual
Containment Level 3 Room Manuals
Molecular Manual
Wash Up Manual
Administration Manual

POCT

Departmental SOP Manuals

The quality manual is reviewed by the PQM and PQF annually or following an adverse event or internally or externally sourced audit which suggests that deficiencies exist or improvements could be made.

The quality manual (and any subsequent revisions) is circulated to all laboratory staff electronically via Q-Pulse – staff are required to read the contents and acknowledge that they have done so.

Service users also have access to the quality manual, via the Trust intranet, from the home page of the pathology website at: <http://www.pch-pathlab.com/cms/>

Document control

This standard is fulfilled by the SOP *Preparation and control of documents*³(GEN-QP-DocCtrl)

³ Available on Q-Pulse

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The master list of all controlled documents is held on Q-Pulse. Each discipline maintains and updates a record of all controlled documents. The PQM is responsible for all aspects of the document control system.

Document preparation and approval

New documents are prepared by relevant competent staff. These draft documents are reviewed and approved using the Q-Pulse approval process by a senior member of the laboratory staff or Clinical Head of Department before issue.

Change and version control

All documents and revisions are controlled via Q-Pulse conformance management software. Changes to existing documents are described on the 'Document Review History' panel which is located on the front page of the SOP template – this information is also recorded within the 'Change details' of the specific document record on Q-Pulse. |

For Q-Pulse the master electronic copies are held on the Trust Q-Pulse server. A full back up is performed by the Trust IT department weekly with incremental back-ups performed daily. Documents accessed via Q-Pulse are presented to users in read only format to prevent unauthorised amendment.

Document review

It is the responsibility of senior technical staff to review all methods and procedures relevant to their area of testing on a regular basis and to ensure that documented methods accurately reflect what is done in practice at all times. Q-Pulse provides alerts to document owners when a document is due for review. Laboratory protocols are updated on a biennial basis whilst other documents, such as risk assessments, are reviewed annually in order to comply with Trust requirements.

When a new document revision is created the existing copy is stored indefinitely within the obsolete register of Q-Pulse.

Service agreements

The contractual arrangement between the laboratory and its users is defined by the laboratory request form that is completed either electronically via Sunquest Integrated Care Environment (ICE) system or via a manual request form.

Each request form (together with its relevant primary samples) is checked for conformity with the laboratory's labelling requirements which are made available to users via the laboratory's internet website. If the form or samples do not meet these requirements then the request may be rejected, the user notified of this and a repeat sample requested. For samples that cannot readily be replaced that were procured within the Trust the form and samples will be quarantined and the user notified to attend the laboratory to address any labelling deficiencies. For samples that cannot readily be replaced that were procured outside of the Trust the form and samples will be returned to the user along with details of the deficiency and the user requested to

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address the deficiencies and return the form and samples back to us when this has been achieved.

The procedure for review of service agreements has been established as part of Trust requirements and via the *SLA Procedure* (Q-pulse: GEN-MP-SLA).

Formal contract reviews occur at least annually to ensure that user satisfaction is being maintained.

The review also ensures that the requirements of both parties are adequately defined, documented and understood.

The contract review process includes the following:-

Analysis of User Surveys

User surveys are performed at least annually. Results from the user surveys are used wherever possible to determine key objectives for the following year.

User complaints

Records of service user reviews, and individual complaints, are held within the A: drive with restricted access, together with a record of any actions stemming from these meetings.

Examination by referral laboratories

The general requirements for sample referral to reference laboratories are described in the *Referral to other laboratories* SOPs (Q-pulse: GEN-QP-Referral). This is then supplemented by more detailed departmental methods. All procedures adhere to current UN 3373 and P650 regulations for the transportation of samples.

Referral facilities are only used:

- When the requested test or examination procedure is outside of our stated repertoire and to undertake the test in-house would be inappropriate in terms of ensuring the quality of the result and / or it would be economically non-viable.
- To provide an expert opinion on a case initially tested and reported by the laboratory.

Laboratory Management are responsible for selecting and monitoring the quality and competency of referral laboratories and consultants on an ongoing basis.

Wherever possible samples are referred only to those laboratories that are BS EN ISO 15189:2012 accredited. Ideally, referral laboratories which are not accredited, will be working towards BS EN SO 15189:2012 accredited status. Turnaround times produced by referral centres are checked periodically. Annually referral centres are checked against the UKAS website to ensure continuing compliance against the

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relevant standards such as BS EN ISO 17025:2017, BS EN ISO 15189:2012 and BS EN ISO 17043:2010. Also, if the referral laboratory is not listed as 'Accredited' on the UKAS website, they are requested to produce documentary evidence to demonstrate continued suitable performance in inter-laboratory comparison programmes, staff competency and evidence of meeting stated turn-around-times, for the assay(s) being undertaken.

The NWAFT laboratories retain responsibility for ensuring that the results of tests undertaken by referral laboratories are provided to the test requester.

Any referral tests undertaken are clearly identified as having been generated by the referral laboratory on the report issued to the test requester.

A list of referral centres and facilities currently in use is available as an appendix of this quality manual (Appendix 4) which is available via the Documents Module of Q-Pulse.

External services and supplies

The selection and purchase of laboratory equipment is governed by the *Procurement of pathology equipment* SOP (Q-Pulse: GEN-MP-EqProc,).

An inventory of capital equipment is held within each pathology department.

The selection and purchase of laboratory services and supplies is governed by the *Procurement of services and supplies* SOP (Q-Pulse: GEN-MP-SuppliesProcure,).

Details of the procedures for purchase, receipt and issue of consumables and reagents and verification of identity and condition are in accordance with Trust non-stock Requisition Policy that also includes procedures for Receipt and returns. For further details consult the Trust Standing Financial Instructions (available via the intranet: <http://spsweb:21000/Documents/Standing%20Financial%20Instructions.pdf>)

A list of approved suppliers of equipment, reagents and consumables is kept within the Suppliers Module of Q-Pulse

The performance of these suppliers is monitored annually with the details of this monitoring recorded within the CAPA and Supplier Module of Q-Pulse.

Advisory services

Information for users and patients

Information for service users, such as sample requirements, clinical limitations of specific tests and frequency of performing specific tests, is made available for all users via the Peterborough pathology website at: <http://www.pch-pathlab.com/cms/>, and within the Hinchingbrooke Pathology user Guide, which is accessible via a link on the PCH pathology website, on the Trust intranet using the Hinchingbrooke tab

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Patient information sheets follow the Trust Standard documentation. All patient information sheets are assessed and approved by the Trust Reading Group prior to release for use. This group includes patient representatives.

The laboratory LIMS is set to screen certain analytes, producing alert messages denoting items that require further action.

Interpretative reports and clinical advice are the responsibility of the Pathologists, Clinical Scientists and competent Biomedical Scientists. 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 laboratory results enquiry line at PCH on (01733 678468) or at Hinchingsbrooke on 01480 416151, from where calls can be directed to the appropriate area.

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 sample rejection due to a failure to meet laboratory acceptance criteria.

Resolution of complaints

Complaints are handled centrally by the Trust Complaints Office. They are disseminated via General Managers for departmental investigation.

Where a person wishes to complain they may make the complaint to the complaints manager or any other member of staff. A complaint may be made orally or in writing (including electronically) and where it is made orally, the complaints manager must make a written record of the complaint which includes the name of the complaint, the subject matter of the complaint and the date which it was made. When the complaint is made in writing the complaints manager must make a written record of the date on which it was received.

Where the complaint is made in writing it will be treated as being made on the date on which it was received by the complaints manager.

The Trust has a generic form that staff should complete when taking the details of a verbal formal complaint. This is available as Appendix 1 of the Trust's Complaint Policy available via SharePoint.

The full procedures for this standard are detailed in Trust Complaint Policy available via SharePoint and internal complaint procedure can be found on Q pulse: GEN-QP-Complaints.

The laboratory investigates all complaints received from clients or other parties and any anomalies identified relating to the laboratory's accredited activities. The complaint is stored in an access restricted file in the A: of any such complaints or anomalies and of any actions taken by the laboratory in response.

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For anomalies that arise due to kit or equipment failure, the Trust Medical Devices Group is notified and if appropriate a Generic Technical Problem Report shall be completed and sent and discussed with the Medicines and Healthcare products Regulatory Agency (MHRA).

<http://www.mhra.gov.uk/index.htm>

Records of dealing with complaints and anomalies are dealt with locally but held centrally by the Trust.

All complaints are reviewed at the laboratory management review meeting.

Identification and control of nonconformities

For further details on this standard see the *Evaluation & Quality Assurance SOP* (GEN-QP-EvalQA) and the *Quality Improvement SOP* (GEN-QP-QImprovement) via Q-Pulse

The procedure details the following:

- a) responsibility and authority for the management of nonconformities
- b) the remedial actions to be taken
- c) suspension of examinations and withholding of reports
- d) assessment of the medical significance of any nonconforming examination and where appropriate notification to the requesting clinician
- e) consideration of whether the results of any nonconforming examinations already released are recalled or appropriately identified, as necessary
- f) who has the responsibility for authorisation of the resumption of examinations
- g) the documenting and periodic review of nonconformities by laboratory management to detect trends and initiate corrective action.

Corrective action

For further details on this standard see the *Evaluation & Quality Assurance SOP* (GEN-QP-EvalQA) and the *Quality Improvement SOP* (GEN-QP-QImprovement) via Q-Pulse.

Corrective actions are undertaken for all incidents recorded using the Trust Datix system. The systems and procedures used by the Pathology Department to identify and control non-conformities, as described in section 4.9, ensure where appropriate an investigative process to determine the cause of the problem is in place. The nature of the corrective action depends on the classification of the non-conformity and on the magnitude of the risk to the patient.

Where corrective action proposes change, then such change is authorised as per documented requirements of the change control procedure (see Q-Pulse: GEN-QP-ChangeCtrl).

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Procedures for corrective action include investigation and documentation of the causes of non-conformances. Laboratory Management ensure by review that corrective actions taken are effective by periodic review of the incidents and by trend analysis. Such reviews are incorporated into the monthly Quality Forum and the annual management review meeting.

Where the identification and investigation of non-conformances or the corrective actions performed therein implies non-compliance with the stated policies and procedures of the Quality Officer for that department may instigate a quality audit of the appropriate area or activity. The results of such audits are part of the quality management system review.

Preventative (PREVENTIVE) action

For further details on this sub-clause see the *Quality Improvement SOP* (GEN-QP-QImprovement) via Q-Pulse

Preventative actions are firmly embedded within the QMS.

Examples include:

System:

- Pre-analytical quality monitoring
- Equipment error monitoring
- Monitoring of user enquiries
- Key performance indicators
- Training
- Risk Assessment
- H&S inspection
- Performance of quality audits and the implementation of action of recommended findings (previously observations) arising from these audits.
- Equipment maintenance & Calibration
- Internal QC & QA
- Inter-laboratory comparison programme data (EQA)
- Communication meetings
- Checklists – e.g. for equipment procurement to ensure that all required records are satisfactorily updated when a new piece of equipment is purchased.

The purpose of the above processes is to promote experiential learning amongst staff.

The outcomes of internal audits, preventative and corrective actions, are communicated to staff in order to encourage staff to consider other initiatives and seek opportunities for further preventive actions.

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Continual improvement

All standard operating procedures are reviewed regularly as per the requirements of the *Preparation and Control of Documents* SOP (GEN-QP-DocCtrl) on Q-Pulse, in order to ensure the accuracy of the content and also as an opportunity to identify potential sources of improvement in Quality Management or Technical Practices. All suggested changes are logged via the Change request facility within the Q-Pulse Document Module.

Actions taken to improve the quality of service are periodically reviewed for effectiveness. Such reviews include monitoring the levels of non-conformances traceable to the area or activity the quality improvement action is associated with.

The Laboratory has produced a number of performance indicators, which are used to monitor the Laboratory's contribution to patient care and also to indicate future quality objectives and performance improvements.

User feedback is also obtained on a regular basis with any opportunities for improvement stemming from these surveys explored to ensure that the service is responsive to user needs and requirements.

The Laboratory is also committed to ensuring that staff feel suitably empowered to make suggestions for quality improvement – they can make these suggestions via departmental meetings, in one to one discussions with senior staff or by raising a 'change control' request via the Q-Pulse CAPA Module.

Control of records

The Laboratory aims to comply 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 Institute of Biomedical Science (IBMS).

The storage facilities for these records provide a suitable environment so that access is restricted and so that loss due to damage or deterioration is minimised.

Please refer to the Laboratory's *Control of Process and Quality Records* SOP (Gen-QP-QARecs) on Q-Pulse, for further details of the documents that are retained and their specific retention periods.

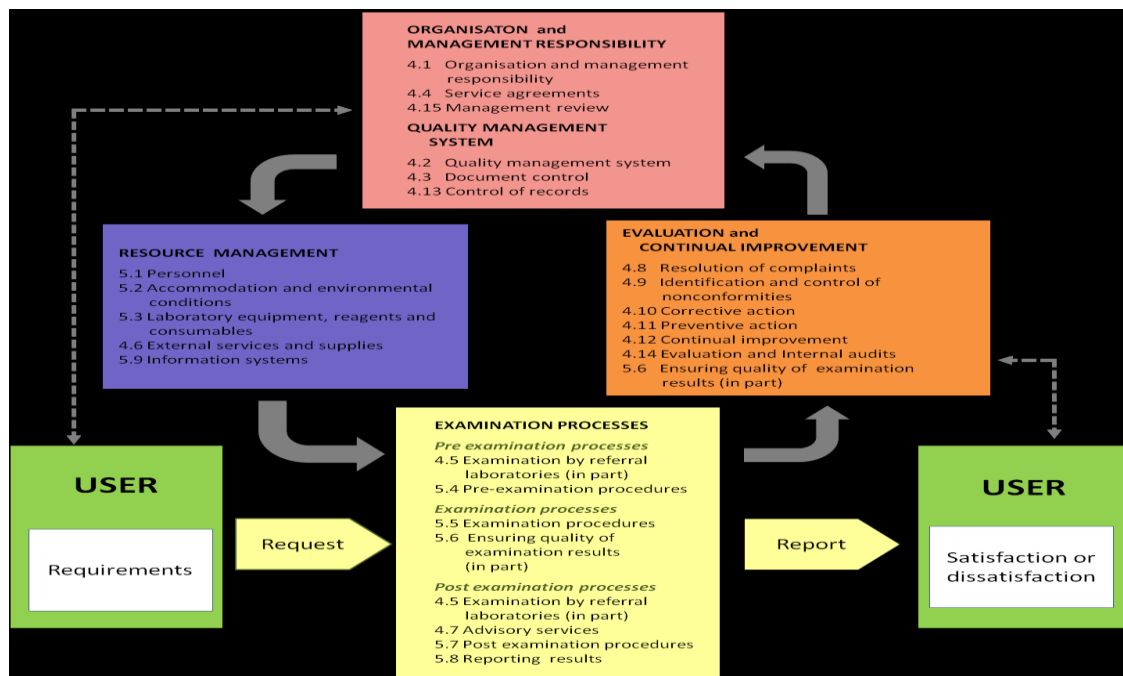
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Evaluation and audits

General

A programme of audits is created annually within each department that aims to audit the pre-examination, examination and post-examination processes.

The Laboratory uses internal audit to provide evidence that the QMS is conformed to, effective, implemented and maintained across all Departments. The Quality Forum has introduced a rolling series of horizontal audits which are used to assess departmental compliance with each of the BS EN ISO 15189:2012 sub-clauses. Assessment audit tool template documents have been devised and are available via Q-Pulse.



The effectiveness of preventative actions, corrective actions and subsequent improvements resulting from these audits is evaluated and monitored as part of management review.

Periodic review of requests and suitability of procedures and sample requirements

Audits of the laboratory's test repertoire occur periodically to ensure that the tests offered remain clinically appropriate for users and the local population.

These audits require suitable consideration of sample volumes, the collection devices used and any preservative requirements to ensure optimal sample collection and preservation of the sample measurand.

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Assessment of user feedback

Regular forums exist for discussion with service users via Multi-disciplinary Team meetings (MDTs), formal contract review meetings, and Hospital Transfusion Committee (HTC) and Human Tissue Authority (HTA) meetings.

In addition, service user opinion is canvassed annually by means of user survey. Together these provide ample opportunity for users to offer feedback on the quality of service being provided and in addition provide opportunities to consider service improvement suggestions.

Staff suggestions

The Laboratory is committed to ensuring that staff feel suitably empowered to make suggestions for quality improvement – they can make these suggestions via departmental meetings, in one to one discussions with senior staff or directly to their departmental manager via the change control request template within the Q-Pulse CAPA Module.

Internal audit

The designated Quality Officers under the guidance of the Quality Manager decide upon the programme of audits to be carried out within their respective areas. Audit officers are required to familiarise themselves with the Laboratory's quality system and have received training in auditing techniques. All staff within pathology are encouraged to undertake training in audit and participate in audit activity.

Wherever possible, auditors will be independent of the laboratory area being audited in order to provide objectivity and impartiality.

Nonconformities identified from these audits are recorded via the Q-Pulse CAPA Module. Root cause analysis of any identified nonconformities will be undertaken and agreed corrective or preventive actions will be recorded within these records.

For further details on the performance of audits please see the Laboratory *Quality Audit Manual* (GEN-QP-AudMan) which is available via Q-Pulse..

Risk management

A comprehensive risk assessment process is in place which considers risk to service provision as well as to health and safety associated risks. Any significant or high risks are recorded via the Trust Risk Register with regular updates provided to Trust Management on any progress taken to mitigate these risks. Any audit findings which have a potential impact upon patient safety are prioritised for urgent action in order to mitigate this risk. Any corrective or preventative actions are recorded within the appropriate CAPA record on Q-Pulse.

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Quality indicators

The laboratory has determined a number of quality indicators which are used to evaluate performance in pre-examination, examination and post-examination processes.

The indicators include stated turnaround times for examinations which have been determined in discussion with service users.

For a description of the indicators currently in use please see the *Quality Improvement* SOP (GEN-QP-QImprovement) on Q-pulse

These indicators are reviewed annually as part of the annual management review and updated accordingly and based upon user feedback. Feedback on performance of these indicators is also used to assist in the determination of laboratory quality objectives.

Reviews by external organizations

Any nonconformity identified following a review of the laboratory service undertaken by an external organization is recorded using the Q-Pulse CAPA Module, and the resulting corrective actions recorded here as for other nonconformities that are identified within the QMS.

Currently the laboratory / host Trust is assessed by the following external organizations:

- Care Quality Commission (CQC)
- Health & Safety Executive (HSE)
- NHS Litigation Authority (NHSLA)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Human Tissue Authority (HTA)
- United Kingdom Accreditation Service (UKAS)

Full details of the regulatory, accreditation and other approval bodies that the laboratory interacts with are contained within an appendix of this quality manual (Appendix 5) which is available via the Documents Module of Q-Pulse

Management review

MGC reviews performance of the QMS on an annual basis as part of its formal Management Review (AMR).

During this the following elements are considered:

- the periodic review of requests, and suitability of procedures and sample requirements
- assessment of user feedback

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- staff suggestions
- internal audits;
- risk management
- review of previously set quality objectives and setting of new objectives.
- use of quality indicators and the appropriateness of these in terms of assessing the laboratory's contribution to patient care.
- reviews by external organizations
- results of participation in inter-laboratory comparison programmes including (EQA) performance.
- monitoring and resolution of complaints
- performance of suppliers
- identification and control of nonconformities including the causes of nonconformities and patterns or trends which highlight potential process problems.
- results of continual improvement including current status of corrective actions and preventative actions
- follow-up actions from previous management reviews;
- changes in the volume and scope of work, personnel, and premises that could affect the quality management system;
- recommendations for improvement to the quality management system, including the impact upon the quality policy, quality objectives and technical requirements.
- Review of on-going training and education programmes.

The findings of the AMR are formally documented and forwarded to Pathology MGC for formal ratification subsequent to publication within the Documents Module of Q-Pulse. The quality objectives generated as a result of the AMR and monitored via the Pathology Quality Forum.

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TECHNICAL REQUIREMENTS

Personnel

For further details on the laboratory's compliance with this standard please see the *Personnel Management* SOP (GEN-QP-PersonnelMgt) which is available via the documents module of Q-Pulse

General

The Trust's Human Resources (HR) Department has developed a comprehensive portfolio of procedures for personnel management. These policies are available to all staff on the Trust Intranet site. In addition the Family and Integrated support services Division (FISS) to which pathology belongs also has its own designated Human Resources Business Partner (formerly HR Manager) and HR Advisor who provide support and advice on HR matters.

Personnel qualifications

The Laboratory has documented the personnel qualifications required for each employment grade – the details are contained within *Personnel Management* SOP which is available via the documents module of Q-Pulse.

In accordance with the Trust's *Professional Clinical Registration Policy* (accessible via SharePoint) staff that are employed to grades where mandatory registration is required (e.g. registered nurse, doctors, clinical scientists and biomedical scientists) are required to provide documentary evidence of their registered status to the HR Department upon appointment. Evidence of continued registration status is then managed centrally by the Trust for medical and dental staff and for those bank or agency staff that are sourced using the Trust's Flexible Staffing Service (FSS). For all other staff groups the process is managed at Directorate level.

Staff are aware that it is their responsibility to maintain their registered status and that a failure to do so will result in the Trust preventing them from undertaking any duties where registration is required and that the HR Department will be consulted regarding suitable action to be taken to address the lapse in registration.

Job descriptions

Each member of staff has a contract of employment and job description which detail their major responsibilities and requirements.

The employee signs both of these records and the Pathology or Departmental Manager holds copies in personnel files.

Laboratory clinical leads have job descriptions on QPulse GEN-MF-JDclinicallead.

Personnel introduction to the organizational environment

In accordance with the Trust's Induction Policy (available via SharePoint) it is a mandatory requirement that all staff that are new to the Trust attend for Trust induction.

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The Trust induction programme is in 2 parts. *Welcome to our Trust* is a half-day session and is mandatory for all permanent staff to attend. It provides a high quality and comprehensive introduction to the NHS and the Trust. Sessions are run on a minimum of 1 per month to ensure it has taken place within an individual's first month at the Trust. The second part is a work area local induction, a checklist for this must be completed within the first 3 months of employment. The Departmental Manager or Training Officer must notify the Trust Learning & Development Department once the local induction has been completed.

All new members of staff undergo an induction programme appropriate to individual needs and designed to meet the following aims:

- To welcome staff into the laboratory and reduce the stress associated with commencing new employment
- To integrate employees into the laboratory quickly and efficiently
- To ensure staff understand the laboratory safety policies
- To ensure that staff are aware of and understand the Pathology QMS and their responsibilities associated with it.
- To give staff a clear understanding of their role and responsibilities
- To familiarise staff with personal and laboratory objectives
- To introduce existing staff to new personnel
- To identify immediate and future training needs

The *Pathology Local Induction Policy* (GEN-TRN-001) is available via Q-Pulse which details the information to be provided during the induction process.

Effective induction is the responsibility of the Departmental Head but the delivery of this is usually delegated to Departmental Training Officers. The Departmental Head signs the induction record sheets once they are satisfied that induction has been carried out satisfactorily. This is countersigned by recipients.

Departmental induction training normally occurs within the first few days at work. A programme is arranged with the Departmental training Officer in order to provide a smooth induction process. Trust induction is provided as soon as possible after the start date.

Supporting documentation is issued during the induction process and recorded on the induction record sheets. The Training Officer will meet with the new members of staff within the first month of induction to deal with any unresolved issues. Local and Trust Induction records are held in their staff competency record.

Specialist Registrars have a planned induction programme.

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Training

This standard is fulfilled by the provision of the *Pathology Training Policy Statement* (GEN-TRN-PolStatement) and the *Pathology Education Support Policy* (GEN-TRN-Policy), both available via Q-Pulse.

Personnel that are undergoing training are supervised at all times.

The PSM has overall responsibility for the delivery of all training undertaken in the laboratory. Departmental Training Officers are responsible for ensuring the existence of documented training programmes and liaison between professional bodies and local education providers. The effectiveness of the training programmes offered are reviewed as part of the departmental management reviews and following feedback from assessments undertaken by external agencies.

Competence assessment

All laboratory areas operate a system of competency assessment to provide evidence that staff have received suitable instruction and are suitably knowledgeable in the performance of procedures. These assessments are repeated at periodic intervals and during some in-house audits to ensure that the procedure is being performed to the appropriate standard and to check that the operator's knowledge remains current.

Reviews of staff performance

Laboratory management operates both an informal and formal responsive approach to individual staff needs. Staff can freely discuss their needs with senior laboratory staff on a day-to-day basis. This system is effective in dealing with immediate needs and this is supported by the Trust's *My Performance Appraisal* (MPA) annual appraisal session.

An annual joint assessment is held between employees and line managers with the aim of identifying strengths and weaknesses, training needs, personal objectives for the year and facilitating actions to satisfy these needs. The Trust's *Appraisal & Development Policy* is available via SharePoint. Annual appraisals take place between staff and line managers with at least yearly objectives being set. Copies of appraisal records are held in personnel files and a copy is provided to the member of staff. The Trust provides appraisal training for managers.

Continuing education and professional development

Details of staff training & education are available via the *Pathology Training Policy Statement* (GEN-TRN-PolStatement) and the *Pathology education support policy* (GEN-TRN-Policy). The Trust requires that all staff participate in continuing mandatory education for elements such as patient safety, fire safety, information governance, hand hygiene, child protection training, and the protection of vulnerable adults, equality and diversity awareness training and PREVENT training. Some of these require update training on an annual or triennial basis. In addition, the laboratory provides programmes of on-going professional development that are all

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staff are given the opportunity to attend, a review of the effectiveness of these programmes is considered within the departmental management reviews.

Personnel records

Employee personal information in accordance with BS EN ISO 15189:2012 requirements is recorded in Personnel Files held by the Departmental Manager.

All staff have the right to examine personnel records of data kept by the Trust that refer to them. (*See Trust policy on SharePoint Access to Personal Files.*)

Some of the records listed within ISO section 5.1.9 may also be held by

- The Safety Officer
- The Occupational Health Department
- By staff in the workplace
- The Trust Fire Officer

Accommodation and environmental conditions

General

The laboratories are organised to provide a safe working environment and to comply with appropriate Health and Safety legislation. All laboratory areas receive conditioned air as provided by the Hospital Building Management System in order to facilitate the correct operation of analysers.

The following specific functions are designated:

- Containment level 3 laboratory (*see Containment Level 3 Manual, Microbiology*)

PCH Access:

All departmental staff and the designated cleaning and portering staff are allowed access to the laboratory.

All others (visiting maintenance personnel and other visitors to the department) are only allowed access following approval and must not be left unaccompanied.

Visiting Maintenance Personnel must report to Brookfield Multiplex Services and obtain permission to work prior to undertaking any work within the laboratory.

Visitors are expected to sign the visitor's book on arrival and to wear a 'Visitor' badge whilst in the department. Anyone not following this procedure shall be challenged by a member of staff to determine the reason for their presence.

A security service is available for on call staff with the issue of lone worker devices, from which calls for help or assistance can be made.

Access to non-public areas at PCH is controlled by swipe card access doors. Pathology is situated on the fourth floor and access to all of the laboratory areas is also swipe card access controlled.

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Bereavement Centre

Entrances to the PCH bereavement centre is via swipe card access only.

Stamford Phlebotomy

The entrance to the phlebotomy suite is kept locked at all times when staff are not in attendance.

Hinchingbrooke Access:

Only departmental staff have access to the laboratory areas, with cleaning and research staff requesting access as required. Access to all the non-public areas is controlled by either swipe card or keypad.

Visitors are expected to sign the visitor's book on arrival and to wear a 'Visitor' badge whilst in the department. Anyone not following this procedure shall be challenged by a member of staff to determine the reason for their presence.

Visiting Maintenance Personnel must report to the hospital facilities department and obtain permission to work prior to undertaking any work within the laboratory.

The Body store has swipe card access for bereavement and mortuary staff and nominated porters. A door bell is provided for others to request attention / access during core hours.

The outpatient Phlebotomy room at Hinchingbrooke and the Phlebotomy team room situated in the Blood Sciences department are secured by key lock. The outpatient key is collected daily from the Kier porters and signed for. The team room key is located within the swipe card access laboratory key cupboard.

Laboratory and office facilities

The facilities have been created with the express purpose of providing a suitable environment for the receipt, testing and reporting of patient samples.

The access control systems are designed to ensure that only staff with suitable authorisation are permitted unescorted access to laboratory areas.

The physical laboratory has been designed to provide the correct environment for sample testing to take place and is compliant with local and national guidance and legislation for these type of facilities.

The facilities themselves have been designed to ensure provision of the following:

- adequate lighting
- adequate power supply (including contingency)
- adequate ventilation
- adequate water supply
- adequate waste disposal
- adequate staff communication systems (via VOIP telephone and Trust email systems)

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- suitable safety systems (such as fire detection and alarm systems, fire-fighting equipment, emergency release door-mechanisms for cold-rooms, emergency drench showers and eyewash facilities)

Storage facilities

The storage of records complies with the *Guidelines for the Retention and Storage of Pathological Records, Archives and Specimens* published by the Royal College of Pathologists (RCPATH).

At PCH, this is available via a link to the RCPATH website via the Q-Pulse Documents Module (document reference GEN-EXT-001).

At PCH, Haematology, Clinical Biochemistry and Immunology, POCT, Microbiology, and Cellular Pathology storage information can be found in GEN-QP-QARECS. The storage areas are secure when the department is closed. At Hinchingsbrooke all records are either within the access controlled laboratory or locked into the nominated archive areas for the department.

Blood Transfusion Records are stored for 30 years minimum. Initially, at PCH, records are stored in the 'Blood Transfusion Records' room within the laboratory (room reference 4.PAT.095), and at a later date the oldest of these will be transferred to the Trust's Health Records and Archived Document Storage facility which is located on the Westwood Farm Holdings industrial estate approximately 250 metres from the PCH site. At Hinchingsbrooke the records are located either in the laboratory or in the nominated archive room (HIN01226).

These storage facilities comply with Caldicott Principles, Information Governance and the Data Protection Act.

The storage of clinical samples is always kept separate from those materials used in testing in order to reduce the possibility of cross-contamination. Cellular pathology off site archive is at the CellNass facility.

The bulk storage of flammable liquids and gases is via facilities situated outside of the main PCH/ Hinchingsbrooke buildings. Quantities of flammable liquids required for daily use within laboratories are kept inside purpose designed metal flammable store cabinets and are returned to these units for temporary storage. Waste flammable liquids are also stored temporarily in these cabinets until then can be transported by Soft FM staff to the external store. Waste flammable liquids are only removed from the Trust site using approved and licensed waste consignors.

The following storage facilities are also provided:

- Refrigerators (4°C) for clinical samples
- Cold rooms (4°C) for storage of kits and reagents
- -20°C and -80°C storage for samples, cultures and reagents

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- Room temperature storage in locked stores
- Hazardous substances are segregated according to their classification either in the lockable flammables store and, laboratory flammables cabinets or poisons cabinet.
- Separate storage for blood and blood products is provided which comply with specific regulation for this material.
- Reagents, calibrators and quality control material are stored in appropriate conditions according to instructions

All freezers and refrigerators are temperature monitored and records retained

Staff facilities

The laboratory sites provide adequate staff toilet facilities and basic catering facilities within a separate rest room area. Full canteen facilities are also available on the site. The laboratory is provided with:

- Areas for hanging laboratory coats
- Storage area for clean laboratory coats
- Lockers for staff to store personal belongings
- Wash hand basin facilities
- Shower facilities
- A meeting room for meetings / seminars.
- A quiet room for interviews and study.

Patient sample collection facilities

There is full patient access to Phlebotomy at Stamford and Hinchingsbrooke including disabled access. The waiting area is separate from the phlebotomy room where samples are procured. Within the phlebotomy room each phlebotomy station is segregated off so that patients are afforded suitable privacy. Access to toilet facilities and also to emergency first-aid if required is provided via the Out-Patients Department which is situated very close to the phlebotomy facility.

The sample collection facility used for blood samples (Sarstedt-Monovette) has been selected due to its superior sample collection performance, high level of patient comfort during the procedure and its lack of adverse effect on the quality of result produced following testing.

Facility maintenance and environmental conditions

Staff are required to maintain good housekeeping throughout the laboratory at all times. The environment is required to be kept clean and tidy, in a manner that is compatible

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with the level of safety required for the operation of a laboratory handling samples for biological examination.

The laboratory requires the monitoring, recording and control of environmental conditions wherever they may impact upon the quality of the result obtained. Where the data from such recording are out of specification and there is an impact on the quality of the product or service provided then a nonconformity is raised via the Q-Pulse CAPA Module and any necessary corrective actions taken.

Quiet environments are provided in certain laboratory areas e.g. histology dissection room, so that the quality of work generated within these areas is not unduly affected by background noise or frequent interruptions.

Laboratory equipment, reagents and consumables

Equipment

The selection and purchase of laboratory equipment is governed by the *Procurement of Pathology Equipment* SOP (Q-Pulse: GEN-MP-EqpProc,).

Laboratory Management aims to ensure that the necessary resources are available through capital and material budgetary submissions. Only equipment fit for its intended purpose is used by the Pathology Department including equipment used for point of care testing.

The laboratory submits periodic requests for equipment replacement to the Trust Investment Appraisal Group in order to ensure that systems are kept up to date and prior to service quality being impaired due to poor performance. Increasingly the laboratory is obtaining major equipment as part of a Managed Equipment Service (MES) – as part of this there is a commitment from the supplier to provide on-going software and hardware safety enhancements and at year 5 to discuss technology upgrades / refreshment.

Before new electrical equipment is put into routine use it is suitably electrically safety tested by Asterol / Brookfield Multiplex at PCH, or the facilities department at Hinchingsbrooke, as per Trust requirements. The equipment will then undergo checking to verify that it is achieving the required performance in accordance with the *Validation Overview* SOP (Q-Pulse: GEN-QP-Validation). Individual laboratory departments have more detailed procedures covering this requirement. The records of equipment verification are kept within individual departmental records or on the Asset Module of Q-Pulse or Document module..

Individual equipment is uniquely labelled with the supplier's serial number so that each can be definitively identified. Manufacturer equipment operation manuals are held within laboratory departments.

After installation, full operator training is carried out either on site, at the instrument manufacturer's premises or at another laboratory. All new instruments come with a

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minimum of one year's parts and labour warranty. After this initial period, either a service contract for preventative maintenance is set up or forms part of the managed service contract.

Any item of equipment that suffers damage or that shows signs of malfunction, or that is shown by calibration or otherwise to be defective and unfit for use shall immediately be withdrawn from service and labelled accordingly. Alternative arrangements shall be made until the item has been repaired and re-calibrated as appropriate. All such actions are recorded in the equipment manual or asset module in Q Pulse.

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

A copy of competencies for staff in relation to equipment is kept as part of the individual's Training Record. This is in three stages

- Primary Training
- Competent to Use
- Basic Maintenance (if separate to full competency record)

An inventory of capital equipment is held within each pathology department or on the Q-Pulse Asset Module.

Individual laboratory departments have procedures for the calibration of equipment that may directly or indirectly affect patient examination results. These procedures have been designed to ensure that the following criteria have been considered:

- Conditions of use and the manufacturer's instructions.
- A record of the metrological traceability of the calibration standard and the traceable calibration of the equipment
- Verification of the required measurement accuracy and the functioning of the measuring at defined intervals.
- Ensuring that, where correction factors are applied as a result of calibration, any previous calibration factors are suitably updated.
- Ensuring that staff are aware that subsequent tampering or adjustment may invalidate any examination results achieved.
- If required, metrological traceability shall be to a reference material or reference procedure of the higher metrological order available. Where this is not possible or relevant, then other means for providing confidence in the results will be applied, for example:
 - The use of certified reference materials
 - Examination or calibration by another procedure

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- Mutual consent standards or methods which are clearly established, specified, characterised and mutually agreed upon by all parties concerned.

Records of the calibration status of equipment and the date of recalibration are kept within individual departments or are available via the Asset Module of Q-Pulse.

All pipettes that may directly or indirectly affect patient results are traceably serviced & calibrated by an external agency on an annual basis. Only contractors that are accredited to BS EN ISO 17025:2017 and whose listed scope (witnessed via their own certificated evidence or via the UKAS website if a UK based company) will be selected to carry out the work.

All centrifuges are serviced by an external agency on a 6 monthly basis. Where specific spin speeds are required for specific examination procedures then the centrifuge spin speed will be traceably calibrated by an external agency whose listed scope (witnessed via their own certificated evidence or via the UKAS website (if UK based company) demonstrates that they are accredited to undertake this work in accordance with BS EN ISO 17025:2017 accreditation requirements. All thermometers are calibrated against a metrologically certified reference thermometer upon acquisition and, as a minimum, on an annual basis thereafter.

All Blood Bank alarms at PCH are monitored by Brookfield Multiplex and by the Estates Department at Stamford. In addition, all of the Trust blood-banks are monitored using the Checkit (formerly Tutela) system.

Records of maintenance and equipment failure are kept in the equipment inventory file kept locally within the department or on Q-Pulse. Files contain a full history of the piece of equipment and include copies of operator instructions, their unique identification, location, maintenance and monitoring record sheets. Details of technical characteristics may be found in either the manufacturers manuals or supporting in-house documented procedures.

Any defective equipment is immediately withdrawn from service and clearly labelled to show that it must not be used. Checks are made to assess if the defective equipment has had any impact upon examinations undertaken prior to the defect being discovered. If so, suitable remedial and corrective actions are undertaken. Upon suitable repair of the equipment verification checks will be made to ensure that it is working within the specified acceptance criteria prior to return to routine use.

A *Declaration of Contamination Status* form must be completed prior to an engineer commencing work on any equipment. This is contained as Appendix 3 within the *Policy for decontamination (cleaning, disinfection and sterilisation) of re-usable medical devices and equipment* which can be accessed on the trusts intranet.

Adverse incidents associated with the use of equipment are recorded as nonconformities using the CAPA Module of Q-Pulse and these are assessed periodically for trends. In addition, any equipment failures which have resulted in the generation of incorrect results will also be logged via the Trust Datix adverse event reporting system. A serious equipment failure or trends that indicate equipment

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issues will be alerted to the equipment supplier and also to MHRA or HSE if necessary.

Records for equipment that contributes to the performance of examinations are kept within individual departments or on the Asset Module of Q-Pulse. As a minimum these records detail the following:

- Identity of the equipment.
- The manufacturer's name, model and serial number or other unique identifier.
- Contact information for the equipment supplier
- Date of receipt into the laboratory and the date the equipment entered into use.
- Details of where the equipment is located within the laboratory.
- Equipment condition when received, i.e. new, used or reconditioned.
- Manufacturer's instructions
- Records that confirm the equipment's initial acceptability for use.
- Maintenance record including any preventative maintenance performed.
- Performance records that confirm the equipment's ongoing acceptability for use. This must include:
 - Copies of calibration reports / certificates.
 - Verification data including dates, times and results.
 - Adjustments made.
 - Acceptance criteria
 - Date of next calibration and / or verification.
- Record of any damage, malfunction, modification or repair.

These records are held indefinitely within Q-Pulse or, as a minimum, with the times stated within the *Control of Records SOP* (GEN-QP-QARecs) .

Reagents and consumables

The selection and purchase of laboratory services and supplies is governed by the *Procurement of services and supplies SOP* (Q-Pulse: GEN-MP-SuppliesProcure,). Further details of the receipt, storage, acceptance testing (where relevant), inventory management and issue of consumables and reagents and verification of identity and condition are detailed within individual departmental SOPs and are in accordance with the Trust non-stock Requisition Policy that also includes procedures for Receipt and returns. For further details consult the [Trust Standing Financial Instructions](#) (available via the intranet).

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The laboratory will use outside services and supplies of adequate quality to sustain confidence in the laboratory's test results. When purchasing services such as calibration then preference will be given to suppliers who are listed as being in compliance with the accreditation requirements of BS EN ISO 17025:2017 for the scope of calibration required. All commercially sourced goods, kits and reagents will be CE marked or UKCA wherever possible.

The laboratory will determine the status of any new outside services and supplies that it employs. Where no independent assurance of the quality of support services or supplies is available, necessary validity checks, calibrations or other actions shall be carried out as appropriate, to ensure that purchased goods comply with specified requirements.

Reagents and consumables are stored according to manufactures' descriptions and the details of batch numbers (where present) are recorded. On major instrumentation on-board systems record the data for quality control reagents automatically.

Handling and storage precautions are assessed using the COSHH procedure. The Trust uses the SYPOL system which requires completion of a Chemical Exposure Scenario (CARQ) Form (available via the intranet). This works in conjunction with a workplace risk assessment.

New lots or shipments of examination kits, or new formulations of kits which have a change in reagent or procedure are verified for performance before they are used for patient samples. A similar approach is adopted for changes in consumables that may affect the quality of examinations.

Each laboratory department utilises its own system of inventory control for reagents and consumables. Any uninspected or unacceptable items are kept separately from those that have been deemed acceptable for use. Instructions for the use of reagents and consumables are available via Q-Pulse/ or via hard-copy laboratory method SOPs.

Adverse incidents associated with the use of specific reagents or consumables are recorded as nonconformities using the CAPA Module of Q-Pulse and these are assessed periodically for trends. In addition, any failures which have resulted in the generation of incorrect results will also be logged via the Trust Datix adverse event reporting system. A serious failure or trends that indicate persistent quality issues will be alerted to the equipment supplier and also to MHRA or HSE if necessary.

Records of reagents and consumables that contribute to the performance of examinations are kept within the individual laboratory departments. These records include the following: (5.3.2.7)

- Name of the reagent or consumable.
- Manufacturer's name and batch code or lot number.
- Contact details for the item supplier
- Date of receipt
- Date of expiry (if applicable)

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- Date entered into service.
- Date material was taken out of service (if applicable)
- Condition when received (e.g. acceptable or damaged)
- Manufacturer's instructions (if applicable)
- Records of confirmation of acceptance for use.
- Records that confirm the reagents or consumables on-going acceptance for use.
- For in-house preparations – details of the person undertaking the preparation and the date of preparation and expiry.

Pre-examination processes

Information for patients and users

The laboratory has produced comprehensive information for its patients and service users. This information is accessible via the following Uniform Resource Locator (URL):

<http://www.pch-pathlab.com/cms/> (PCH)

And using the above link and then clicking on the HH tab (HH)

As a minimum, this information includes:

- Location of the laboratory.
- Types of clinical service provided, including the examinations referred to other laboratories.
- The laboratory service hours.
- Range of examinations offered by the laboratory. This includes:
 - Sample requirements
 - Primary sample volumes
 - Result turnaround times
 - Biological reference intervals
 - Clinical decision values.
 - Any special precautions.
- Instructions for suitable completion of request forms
- Instructions for preparation of the patient
- Instructions for samples collected by patients – these patient information leaflets are provided by the Trust's document library facility.

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- Sample transport instructions – including any special handling needs
- Requirements for patient consent (if required)
- Criteria for the acceptance and rejection of samples.
- Factors known to significantly affect the performance of the examination or the interpretation of the results.
- Availability of clinical advice on ordering examinations and on the interpretation of results.
- Laboratory's policy on the protection of personal information (Trust Information Governance Policy)
- Laboratory's complaint procedure (Trust complaints procedure)

Request form information

Request forms are designed to provide all relevant information required to provide a safe and meaningful report including clinical advice and to satisfy internal audit requirements.

The laboratory's request form requires the following information to be provided:

- Patient identification. This includes:
 - Patient name
 - Gender (Assigned at birth)
 - Date of birth
 - Unique identifier (e.g. Hospital DIS number, or NHS Number)
- Patient location details.
- Name of the requesting clinician.
- Result destination and contact details.
- Type of primary sample
- Anatomic site of origin, where relevant (e.g. within histopathology)
- Instructions for suitable completion of request forms
- Examinations requested.
- Clinically relevant patient information (e.g. patient's family history, travel and exposure history, communicable diseases).
- Date and (where relevant), the time of primary sample collection.
- Date and time of sample receipt.

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At PCH requests for laboratory investigation are produced using the Sunquest Integrated Clinical Environment (ICE) Order Communications Module. This facility allows users to be able to view all of a patient's results irrespective of whether they have been requested within the Trust or by GP. For service continuity purposes, should access to the ICE system be unavailable then separate departmental manual request forms are in use for haematology and blood transfusion, biochemistry and immunology, microbiology, histopathology and non-gynaecological cytology investigations.

In addition, urgent tests can be requested verbally but these must then be confirmed by an electronic ICE request.

At Hinchingsbrooke appropriate request forms are provided for both in-house and external laboratory testing.

If information on a form provided by a user is unclear or incomplete, a call will be made to the user (if possible to identify) to clarify the situation before completing the examination.

Primary sample collection and handling

This is covered within the *Specimen Information* section of the Pathology User information web pages at: <http://www.pch-pathlab.com/cms/> and within the specific departmental sections of the Hinchingsbrooke Pathology User guide (link on the PCH pathology website).

The information includes instructions on the processes to be followed prior to and during sample collection including the requirements for suitable storage of sample containers prior to use.

The sample collection procedures require that suitable checks are made to establish and confirm the identity of the patient, the labelling requirements to ensure acceptance by the laboratory, storage of procured samples prior to sample transport and the safe disposal of materials used during the sample collection process.

Sample transportation

This is covered in the Transportation Section of the Pathology User Information web pages and Hinchingsbrooke Pathology User guide. Copies of this document have been provided to Medirest who manage the hospital portering team, and to Sodexo and CGS Couriers who are contracted to transport pathology samples between the GP practices and PCH. Transportation to CUHFT is currently contracted by them with CitySprint Couriers.

All pathology samples being transported by road are sealed within a triple layer system with an external rigid container in compliance with UN 3373 requirements.

All PCH GP practices receive at least two sample collections per day – usually aimed towards the end of the morning and afternoon to maximise the samples collected but also to ensure that the integrity of the samples is not impaired due to prolonged storage following procurement. Stamford and Rutland Hospital and North

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Cambridgeshire Hospital (Wisbech) receive three collections due to the volume of samples being procured from these sites. Hinchingsbrooke Hospital area GP's are currently contracted to CUHFT. The transportation of samples collected from these GP's calls to Hinchingsbrooke at least twice daily to deliver GP INR's, Antenatal samples and Urgent Haematology / Biochemistry specifically requested for Hinchingsbrooke Hospital testing.

Sample reception

Procedures for this are detailed within specimen reception SOPs for each laboratory department. In addition, departmental SOPs also detail the criteria required for samples to be accepted for testing by the laboratory and what actions are to be taken for those samples that are rejected for testing. Periodic audits are undertaken to ensure that the laboratory's criteria for sample acceptance and rejection are being adhered to. For samples that do not match the acceptance criteria but are clinically critical or are irreplaceable testing may be undertaken but all results will be issued with an alert indicating the nature of the problem and advising that necessary caution must be applied.

Bar codes or individual laboratory numbers are used for labelling request forms and specimens. All specimens, accompanying request forms and supporting documentation are uniquely identified throughout all stages of investigation by means of the unique laboratory number.

The patient, physician and examination related information on the request form and details of specimens received are entered onto the Laboratory Information Management System (LIMS) (PCH-DXC i.laboratory-TP (Telepath), Hinchingsbrooke – Winpath). For anonymised patients (e.g. from Department Of Sexual Health), the system accepts a number instead of a name.

All sample requests are date and time stamped upon receipt within the laboratory. The entry onto the LIMS system is either automatically dated and timed or entered from the time stamp information, as is the details of the operator undertaking the sample and request registration.

The following utilities are available to reduce errors:

- Hospital patient details are registered against the hospital DIS number at PCH and a unique hospital number at Hinchingsbrooke to enable patient demographics to be called up.
- The DIS number/ unique hospital number is used to access stored patient demographics. (Haematology, Clinical Chemistry, Immunology & Microbiology)
- Cellular Pathology uses a Date of Birth search ('K' search on i.Lab-TP) to search for patients.

The procedures for specimen identification, Specimen rejection, Urgent Specimens and Medico legal specimens are all described in Departmental specific SOPs held on Q-Pulse

For additional information please consult the following laboratory departmental protocols:

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Specimen reception

Sample acceptance/rejection (including unlabelled specimens)

Dealing with urgent requests for examinations.

Danger of Infection specimens

Sample breakage/spillage

Dealing with leaking or broken specimens is also described in the Pathology H&S Manual (ref: HS-H&S-Manual).

Pre-examination handling, preparation and storage

All samples received are stored within the laboratory in compliance with departmental procedures. These procedures are designed to ensure that samples are stored securely and that sample damage, loss or deterioration during pre-examination activities, preparation and storage are minimised.

Time limits for requesting additional or further examinations on already received samples are contained within individual SOPs and also provided to users via the *Specimen Information* section of the Pathology User information web pages at: <http://www.pch-pathlab.com/cms/> and the Hinchingsbrooke Pathology User Guide

Examination processes

Selection, verification and validation of examination procedures

The laboratory only uses examination procedures which have been verified or validated for their intended use.

Prior to validation a set of performance requirements are established based upon the intended use for that examination.

Preference is given to examination procedures based upon:

- Instructions provided for use in *in vitro* medical devices
- Methods published in established / authoritative text-books, peer-reviewed texts or journals, or nationally or regionally agreed methods.
- In-house evaluation data
- Advice from reference laboratory evaluations
- Selection of well-established techniques in use in other laboratories

SOPs with common usage are agreed between departments.

Changes to procedures that may affect testing protocols or result interpretation are notified to all users of the service in advance of any change.

Where examination procedures are being used without deviation from the manufacturer's requirements then the laboratory will independently verify the

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manufacturer's validation performance characteristics prior to introducing the procedure into routine use.

For the following examination procedures:

- Non-standard methods
- Laboratory designed or developed methods
- Standard methods used outside of their intended scope
- Validated methods that are subsequently modified

The laboratory will extensively validate the procedure to ensure that the intended use of this examination has been fulfilled.

For both verification and validation the laboratory will keep extensive records of the testing procedures employed, contemporaneous evidence of the results achieved and evidence of suitable review and acceptance of the data generated.

Testing will be undertaken in accordance with the principles stated within the laboratory's *Validation Overview* SOP (Q-Pulse: GEN-QP-Validation) and the more detailed validation procedures held by individual laboratory departments.

For measured quantity values the laboratory will determine the measurement uncertainty for each examination procedure, will regularly review the estimates for this and aim to minimise the impact of this wherever possible.

The laboratory's estimates of measurement uncertainty can be made available to service users upon direct request to the Pathology Quality Manager.

Further details of measurement uncertainty are contained within individual departmental SOPs for this which are available via the Documents Module of Q-Pulse.

Validation or verification files are generated for examination procedures. Historically these files have been retained within individual departments but new validations / verifications are now stored on the documents module of Q-Pulse for manual methods and the appropriate asset/ equipment record of Q-Pulse for automated methods.

As a minimum these files contain the following:-

- Method Change Control Record Log
- Plan for validation / verification of the test method
- Test method verification data and approvals
- LIMS forms and documentation (as applicable):
 - Copy of test / profile change form
 - Copy of new code request form
 - LIMS enquiry reports, including calculations (if appropriate) and any coded text expansions.

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- Sample report printouts.
- Confirmation that test result correctly shown (including reference ranges) on i.Lab-TP, Sunquest, Winpath and EMIS (Hinchingsbrooke site) and remote systems
- Support documentation for stated reference ranges and clinical alert values if appropriate.
- Method summary report sheet including consideration of uncertainty of measurement.
- Manufacturer's product inset / method sheet
- Details of any correspondence to service users

Biological reference intervals or clinical decision values

Wherever applicable, biological reference intervals have been calculated for examination procedures and made available to service users via the *Specimen Information* section of the Pathology User information web pages at: <http://www.pch-pathlab.com/cms/> and the Hinchingsbrooke Pathology User guide

Biological reference intervals are periodically reviewed (by laboratory staff in liaison with the clinical head of that laboratory department) with respect to:

- Appropriateness to the population served.
- Changes in pre-examination procedures
- Changes in examination procedures

Documentation of examination procedures

A master copy of all SOPs as 'read only' are held centrally on Q-Pulse. Controlled hard-copies are issued to named individuals on pink paper at PCH, and to named section folders at Hinchingsbrooke. Records of all copies and their electronic distribution within the laboratory are held on Q-Pulse. Staff listed on the electronic distribution are required to electronically acknowledge that they are aware and have read the contents of the document.

A master list of documents for all pathology areas is held on Q-Pulse.

An SOP template is available via Q-Pulse to guide authors, containing all main headings that require inclusion.

Ensuring quality of examination results

General

The laboratory aims to ensure the quality of its examinations by performing them under suitably controlled conditions. This aim is supported by:

- A comprehensive quality control approach to pre-testing, testing and post testing processes.

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- The approach to quality control is based on principles of in-process QC checks.
- As well as controlling the tests the key inputs to each process will be reviewed and signed off on a daily basis.

The details of the each laboratory's Quality Assurance programme may be found in the departmental SOPs on Quality Assurance and individual Method SOPs.

Quality control

The laboratory aims to select, wherever possible, quality control materials that will react in a manner as close as possible to patient samples. QC materials are periodically reviewed to ensure that they continue to offer a reliable indicator to examination procedure performance and thereby minimise the risk of production of erroneous patient results. Wherever possible, independently sourced third-party QC materials are used in order to reduce the possibility of bias associated with the use of reagents supplied by the system manufacturer.

Individual laboratory procedures exist to indicate the actions to take to prevent the release of patient results following a failure of QC. The process also details the actions to take regarding the re-examination of patient samples following QC rule violations, including the need to assess samples that have been examined since the last successful QC test.

QC data are also reviewed periodically in order to identify trends that may indicate deterioration in examination procedure performance so that suitable corrective action can be initiated. Trends noted in this way and the subsequent actions are recorded via the CAPA Module of Q-Pulse.

Interlaboratory comparisons

The laboratory aims to participate in third-party external quality assessment (EQA) schemes relevant to the testing repertoire undertaken. Wherever possible, preference is given to EQA schemes that have been assessed against BS EN ISO 17043:2010 or those incorporating *International Laboratory Accreditation Cooperation (ILAC) Guidance 13*.

Where formal inter-laboratory comparison schemes are not available then the laboratory aims to provide objective evidence for the acceptability of examination results via a number of means, including the use of certified reference material, re-assessment of samples previously examined and exchange of samples with other laboratories. In accordance with the UKAS document TPS 47.

Results are either displayed on the laboratory notice board in numerical and graphical format or recorded on Q-Pulse/ and distributed to all staff to acknowledge.

Results are distributed to all departmental senior members of staff and are discussed at the Departmental Staff Meetings. The Pathology Quality Forum is informed via departmental reports of any unresolved issues

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All inter-laboratory poor performance is recorded as nonconformities within the CA/PA Module of Q-Pulse together with a description of the corrective actions taken to reduce the possibility of recurrence.

Full details of the quality assurance schemes that the laboratory currently participates in are available as an appendix of the quality manual (Appendix 6) which can be accessed via the Documents Module of Q-Pulse.

Post-examination processes

Review of results

All reports undergo a data system check (manual or/and computerised) before issue governed by user defined rules. In biochemistry at PCH, most results on NPCL lists (e.g. endocrine and DFTs) are usually authorised by BMS staff using pre-defined criteria initiated by the Consultant Chemical Pathologist and issued to users. Other abnormal results (e.g. U/E) on NPCL are phoned and released exclusively by BMS staff on a 24/7 basis. All other significant positive results are authorised by medical or clinical scientist staff. Certain negative results, selected by the computer using approved, predefined rules, are printed without medical authorisation.

At Hinchingbrooke all biochemistry results are authorised by BMS staff. Comments and reflex testing are added according to pre-defined criteria initiated by Consultant Chemical Pathologists.

Storage, retention and disposal of clinical samples

The control of clinical material is described in the SOP *Control of Clinical material* on Q-pulse (GEN-QP-ClnMtrl). This procedure fully describes how samples are indexed, stored and disposed of in accordance with regulations and national guidance. Retention periods are in accord with *Guidelines for the Retention and Storage of Pathological Records, Archives and Specimens* (Q-Pulse ref: GEN-EXT-001) which is co-authored by the Royal College of Pathologists and the Institute of Biomedical Science.

Reporting of results

Examination procedures provide details of specific reporting requirements. The PCH laboratory issues reports electronically via the Sunquest ICE system.

At Hinchingbrooke results are transferred post authorisation electronically from Winpath to EMIS. Some users still require us to provide them with additional hard-copy versions of these reports and these are printed and distributed via the internal post systems.

In addition, additional supplementary reports are issued following the receipt of reference laboratory results. Where a report delay is thought likely to potentially compromise patient care an interim result may be offered so that service users are fully aware of the progress being made.

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For Hinchingsbrooke an Interim report is not available on Winpath if delays are being experienced in testing/test results this is notified via Comms to the affected clinical areas.

Periodic audits are undertaken to check the accuracy of results that are manually transcribed and also to check the accuracy of electronic results received by service users.

Laboratory reports are formulated to include at least the following data items:

- Name of the laboratory issuing the report
- Identification of any tests undertaken by a referral laboratory
- Patient identification on each page of the report.
- Identification of the requester and the requester's location
- Date of the primary sample and (where appropriate and relevant) the sample collection time.
- The type of primary sample received
- The measurement procedure utilised (if appropriate)
- Examination results reported in SI units, units traceable to SI units, or other applicable units.
- Biological reference intervals (if appropriate)
- Result interpretation (if appropriate)
- Cautionary or explanatory notes
- Identification of the person reviewing the results and authorising the report release
- Date of report and time of release.
- Page number to total number of pages (e.g. Page 1 of 5, etc.)

Release of results

Individual laboratory departments hold departmental procedures which detail who may release results and the process to be followed. These procedures require suitable consideration of the following:

- Indication in the report if the quality of the primary sample received was unsuitable for examination or could have compromised the quality of the result generated.
- Checks to ensure that results are legible and without mistakes in transcription.
- If an examination result falls within established alert or critical values:
 - Has a physician (or other authorised health professional) been immediately notified?
 - Has a record of this action been made which details – the name of the person notified, details of the examination results conveyed, any difficulties encountered in making the notification and the name of the laboratory member who undertook the action?

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- That checks are made to ensure that results are legible, without errors in transcription and that they have been made available only to those authorised to receive them.
- If results are distributed via telephone or some other electronic means then they are only provided to suitably authorised personnel. A record must be kept of all results issued via the telephone (details as shown above) and these must be followed up by the production of a formal written report.

Automated selection and reporting of results

The clinical biochemistry and haematology laboratory departments at PCH currently use a system whereby some reports are selected for reporting automatically. In both areas there are specific protocols which cover how this process occurs.

The procedures consider:

- The criteria to be used for automated selection and reporting have been defined and approved by the clinical head of department.
- The criteria have been fully validated for proper functioning prior to use and are re-validated following system changes or at periodic intervals to ensure suitable functionality is maintained.
- All pertinent staff have been made aware of the procedure to be followed and the criteria to be used.
- The impact that sample interferences (e.g. haemolysis) may have upon the examination results.
- The process for incorporating analytical warning messages from instruments into the automated selection and reporting criteria.
- How results selected for automated reporting can be identified at the point of review, in advance of result release.
- How the process can be suspended rapidly if required.

Revised reports

In circumstances where it is found to be necessary to issue a supplementary report, a new test report is generated in accordance with the agreed departmental SOP. This revised report will make reference to the date and patient identity within the original report. If it is necessary to amend a result, a comment is attached to the result indicating that the result has been amended. If a significant anomaly is identified, the user is contacted and notified of the discrepancy. The revised record on the LIMS indicates the date of the change and the name of the person taking responsibility for this change. The LIMS retains the original version of the report which can be subsequently accessed by those with suitable access rights if required.

Where the laboratory is at fault records of amended results are recorded on the CA/PA Module of Q-Pulse together with an indication of the action taken to reduce the possibility of a recurrence. For clinical area issues the Datix reporting system is used.

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Laboratory information management

Staff are aware that information that they have access to in the course of their duties, regarding patients, contracts and other work matters, must be considered confidential and should not be disclosed to others, except where the third party has need of this information to carry out their duties as an employee of the Trust. As a part of the Trust's Information Governance (IG) requirements all staff are required to undertake mandatory update training sessions on IG.

The laboratory operates in accordance with the Trust's procedures for data security, storage, archive and retrieval of records, electronic passage to remote users and disposal of records.

Data held is subject to legislation under the Data Protection Act that makes it a criminal offence to misuse personal information held on a computer.

Under The Data Protection Act it is a criminal offence to "knowingly or recklessly obtain, disclose or transfer personal data" held on computer-based and paper-based (or manual) data records, and constrains the international movement of such data primarily to the countries of the EC. If these principles are breached, you may be personally liable for committing a criminal offence.

The Trust has stated that staff who have access to computerised personal information related to patients in the course of their employment must regard such information as strictly confidential. Failure to adhere to this policy will be regarded as serious misconduct and lead to disciplinary action, which may lead to dismissal.

The Trust has generated policies for information government and allied these to information leaflets which are all available via the Document Module of Q-Pulse . In addition the laboratory has produced polices for *Patient Confidentiality* and for the *Management of Data and Information* to reinforce these requirements for laboratory staff.

Staff are aware that it is a Trust requirement to keep passwords for access to a computer system secret, that they must not write them down anywhere or divulge them to anyone else. The systems prompt changes in Passwords at regular intervals to maintain security.

At PCH the laboratory utilises the CSC Healthcare Group (formerly iSOFT) i.Laboratory-TP (formerly Telepath) system for data management. The Trust IT Department provides management of the systems with the support of the IT lead within Pathology.

At Hinchingsbrooke the laboratory utilises the Clinisys Winpath v 5.32 system for data management. Support is provided by the Trust IT department and internally by the nominated IT lead. The NPEX system is used for the transfer of work and results from HH and PCH.

Telepath/ Winpath User Manuals are available within pathology. These detail the authorities and responsibilities of all personnel who use the system and focus in particular on:

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- How to suitably access patient data and information
- How to enter patient data and examination results to the required consistent standard
- Who has the authority to change patient data or examination results and how these processes are to be undertaken
- Who has the authority to release examination results and patient reports.

Information system management

LIMS system management requirements are undertaken partly by laboratory staff and partly by the Trust IT department in accordance with an *IT SLA* (ref: GEN-SLA-IT) which is available via the Document Module of Q-Pulse.

The LIMS (i.lab-TP/ Winpath v5.32) have been validated for use within the laboratory. Any upgrades to the system software are thoroughly verified and approved for use prior to introduction by the use of formal change control recording and testing within the training environment that is available within the system. Each laboratory department has a procedure to be followed for testing these upgrades prior to release. All validation data associated with the testing (including any contemporaneous screen shot evidence etc.) are retained within the individual departmental records but over time future records will now be consolidated within the Telepath file record of the Asset Module of Q-Pulse..

Security access to either system is strictly controlled via the Trust IT department security procedures and subsequently via security access control for individual users.

Operational elements of system maintenance are undertaken by the Trust IT Department in accordance with the SLA mentioned above. Electronic data is also backed up by the Trust's IT department in accordance with this SLA.

Periodic audits are carried out to provide an assurance that patient results issued electronically to users are accurately reproduced by the systems external to the LIMS.

In the event of a protracted LIMS or electrical failure then section 3.2 of the *Pathology Business Continuity Plan* (Q-pulse ref: GEN-MP-BsCnPln) will be invoked until such time as there is a restoration of the LIMS. Further details of the general continuity plan and site specific actions can be accessed via the Documents Module of Q-Pulse.

3 REFERENCES

Medical laboratories – Requirements for quality and competence (BS EN ISO 15189:2012).

Point-of-care testing (POCT) — Requirements for quality and competence (ISO 22870:2016)

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Quality management systems – Requirements (ISO 9001:2015)

Blood Safety & Quality Regulations (2005) No. 2898 – available at:

<http://www.legislation.gov.uk/ukxi/2005/2898/contents/made>

Blood Safety & Quality (Amendment) (No. 2) Regulations (2005) No. 50 – available

at: <http://www.legislation.gov.uk/ukxi/2005/50/contents/made>

Blood Safety & Quality (Amendment) Regulations (2006) No. 2013 – available at:

<http://www.legislation.gov.uk/ukxi/2006/2013/contents/made>

Trust Management Human Resources and Health & safety Policies and Procedures
– available via SharePoint section of Trust *iConnect* intranet site.

Peterborough Pathology User Information website – available at: <http://www.pch-pathlab.com/cms/>

Hinchingbrooke Pathology User information document – available at: <http://www.pch-pathlab.com/cms/>

Then clicking on the Hinchingbrooke tab

Trust Raising Concerns in a Safe Environment Policy – available via the Trust intranet site.

Managing Conflicts of Interest Policy- available via the Trust intranet.

4 APPENDICES

All appendices are available as separate documents:

Appendix	Reference on Q-pulse
APPENDIX 1: ORGANISATIONAL CHARTS	GEN-QP-0001D
APPENDIX 2: SENIOR STAFF IN PATHOLOGY	GEN-QP-0001F
APPENDIX 3: COMMITTEES	GEN-QP-0001E
APPENDIX 4: REFERRAL CENTRES USED	GEN-QP-0001B
APPENDIX 5: ACCREDITATION & APPROVAL BODIES	GEN-QP-0001C
APPENDIX 6: QA SCHEMES	GEN-QP-0001G

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