NHS
North West Anglia
NHS Foundation Trust

PATHOLOGY QUALITY MANUAL

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September 2024	Substantial changes to the quality manual in its entirety, to align document with BS EN ISO 15189:2022.	CH/KWW

1 Contents

2 Mission Statement

The Pathology Department 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.

Integral to this is that all laboratory activities are conducted and considered in parallel to all requirements of BS EN ISO 15189:2022, service users, regulatory authorities and other recognised organisations wherever the service is provided.

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 (NWAFT).

3 Purpose/Scope

This document, together with all related procedure manuals, represents the Quality Management System of the Pathology Department, North West Anglia NHS Foundation Trust. The “Pathology Department” describes the laboratories based at Peterborough City Hospital and Hinchingbrooke Hospital, in-patient phlebotomy at Peterborough City Hospital and Hinchingbrooke Hospital, and phlebotomy outpatient clinics at Hinchingbrooke Hospital and Stamford Hospital. This document has been compiled to meet the requirements of the December 2022 publication of BS EN ISO 15189:2022 *Medical Laboratories – Requirements for quality and competence*, and appropriate national and international standards. All procedures herein are mandatory within the Laboratories.

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 contact details of the laboratory sites are:

Peterborough City Hospital
Edith Cavell Campus
Pathology Department
Department 413

Bretton Gate
Peterborough
PE3 9GZ
Tel: 01733 678468

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

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

Core hours for the Pathology Department are 0900 – 1700, Monday to Friday.

An in-house routine diagnostic service for Haematology, Blood Transfusion, Biochemistry and Microbiology is based at Peterborough City Hospital (PCH). This service has extended opening hours to meet service needs, it is supplemented by a night shift running from 20.00 to 08.00 for the testing of urgent samples. This then provides a full 24/7 service provision. Microbiology comprises: bacteriology, virology/serology, mycology, and parasitology.

An in-house routine diagnostic service for Immunology is based at the PCH site. This service is available Monday to Friday, 0800 – 1700.

A routine in-house Cellular Pathology service is provided during core hours at PCH which includes Histopathology and diagnostic Non-Gynaecological Cytology. This service is available Monday to Friday, 0830 – 1700.

The Bereavement Service
and the Body Store at PCH and Hinchingbrooke Hospital is open during core hours Monday to Friday, 0800-1600. A Post-Mortem Suite is based at PCH also operating core hours only. All services are supported outside of core hours via an on-call system.

An in-house routine diagnostic service for Haematology, Blood Transfusion and Biochemistry is based at Hinchingbrooke Hospital, during core hours Monday to Friday 0900-1700. This service is supplemented by a 24 hour out of hours shift system for the testing of samples. Microbiology, Immunology and Histology services for Hinchingbrooke Hospital are provided at PCH.

The NWAFT Point of Care Testing (POCT) Department manages the POCT services for all Trust hospital sites. POCT departmental managers are responsible for monitoring issues relating to governance, quality assurance and training, and for ensuring that the Trust POCT activities meet the requirements of BS EN ISO 15189. POCT support is available on the PCH site Monday to Friday 0800 – 16:30. The Hinchingbrooke site is monitored remotely and a member of staff attends for trouble shooting and training requirements as necessary.

An in-patient Phlebotomy service is operated at PCH on Monday to Friday, 0800 – 1200. A limited morning service is provided at weekends and bank holidays.

An in-patient Phlebotomy service is operated at Hinchingbrooke Hospital on Monday to Friday, 0800 – 1200. A limited morning service is provided at weekends and bank holidays. An outpatient service is provided from 0900 – 1700 at the Hinchingbrooke Treatment Centre on weekdays only, this is only for out-patient generated requests (not GP referrals).

An outpatient Phlebotomy service is operated at Stamford and Rutland Hospital on Monday to Friday, 0830 – 1630.

4 General Requirements

4.1 Impartiality

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

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

It is the responsibility of MGC to eliminate or minimise the effect or any threat to impartiality, and document actions taken to mitigate the threat.

Should competing interests exist, the Trust requires that staff openly declare these via completion of the *Conflicts of Interest Declaration* section of their NHS Electronic Staff Record (ESR), in compliance with the *Conflicts of Interest Policy* (accessible via the Trust intranet). This ESR record can be used to log any personal relationships (including non-financial ones) which might compromise impartiality. The minutes of all meetings held within pathology have a declaration of interest section where staff can raise any competing interests so that they are documented and transparent to all committee members.

A separate Trust *Gifts, Hospitality and Sponsorship Policy* exists with guidance on accepting gifts and donations. The Trust requires that staff openly declare any gifts or donations using the *Gifts, Hospitality and Sponsorship Declaration* form (accessible via the Trust Intranet).

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. Staff should report any concerns of fraud to the Local Counter Fraud Specialist (LCFS), Trust Chief Finance Officer or NHS Fraud and Corruption Reporting Line. Other concerns relating to impartiality (e.g. conflicts of interest, receipt of gifts or hospitality outside of Trust policy) can be raised through the Trust's *Freedom to Speak Up: Raising Concerns in a Safe Environment* policy (accessible via the Trust intranet).

4.2 Confidentiality

The Pathology Department uses the Clinisys WinPath Enterprise (WPE) Laboratory Information Management System (LIMS) for data management. Support for WPE is provided by Clinisys. It is facilitated by their Clinisys customer service management system (ServiceNow), and the Pathology IT Lead. The legally binding agreement for the provision, management and performance of the LIMS can be accessed via Q-Pulse (GEN-MF-SLA-Winpath).

When the release of confidential information is required by law (e.g. Freedom of Information Act requests), access to the information must be requested through the Information Governance Manager. The Trust's commitment to publish information excludes any information which can, legitimately, be withheld under the exemptions set out in the NHS Openness Code or the Freedom of Information Act.

The laboratory is responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities. Personnel that are included in this are committee members, contractors, personnel and external bodies or individuals with access to laboratory information acting on the laboratory's behalf.

In cases where information must be released by law or contractually, the patient concerned shall be notified of the information released, unless prohibited by law. For any case in which it is determined that there has been a breach of patient information the laboratory shall inform users / patients in advance of the information being released to the public domain.

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. This is reinforced through Trust *Information Governance and Data Security* mandatory training (renewed annually), with further local guidance provided in SOPs GEN-MP-PatConf (*Patient Confidentiality*) and GEN-QP-DataMgt (*Management of Data & Information*). Failure to adhere to these policies will be regarded as serious misconduct, which may lead to disciplinary action, including dismissal.

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 UK and countries of the EU. If these principles are breached, staff may be personally liable to prosecution.

4.3 Requirements Regarding Patients

Laboratory management regularly reviews the service provided to ensure that its examination methods and results meet the needs of service users and the patient population served. The well-being, safety and rights of the patient are the laboratory's primary consideration.

Information relating to the department's examination processes and how to obtain results is publicly available on the NWAFT Pathology Services website.

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.

The Trust's *Duty of Candour Policy* (available via the Trust Intranet) ensures that patients and their carers are notified about patient safety incidents, and lessons learned to prevent them from being repeated.

All staff are aware of the need to ensure that patients and their specimens are always treated with respect. This is reinforced through Trust *Patient Safety*; *Safeguarding;* and *Equality, Diversity & Human Rights* mandatory training (renewed triennially).

5 Structural & Governance Requirements

5.1 Legal Entity

The Pathology Department is part of the North West Anglia NHS Foundation Trust (NWAFT). As a recognised legal entity NWAFT can be held legally accountable for all the department's laboratory and POCT activities.

5.2 Laboratory Director

The Laboratory Director is Dr Ashraf Ibrahim who is the Pathology Associate Clinical Director (ACD) and is a Consultant Histopathologist. Dr Ibrahim 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 in the organisation chart GEN-QP-0001D.

The laboratory director is responsible for the professional, scientific, consultative or advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory. Full details of the laboratory director's role and responsibilities are stated in the associated *Laboratory Director* document (GEN-QP-LabDirector).

5.3 Laboratory Activities

The range of laboratory activities provided by the department is provided on the NWAFT Pathology Services website. Activities performed at the Hinchingbrooke Hospital blood sciences laboratory are not currently accredited to BS EN ISO 15189.

The schedule of accreditation to BS EN ISO 15189 for the Peterborough City Hospital Pathology Department can be found on the UKAS website. The department's UKAS customer number is 8055.

The Pathology Department at Hinchingbrooke Hospital is seeking accreditation to BS EN ISO 15189.

Where a laboratory activity falls outside of the UKAS schedule of accreditation, this shall be unambiguously communicated to the requestor via the NWAFT Pathology Services website and/or the result report.

The accreditation status of referral centres and external providers of laboratory services is documented in the *Referral Centres Used* document GEN-QP-0001B.

Information for PCH Pathology Department service users - including sample requirements, clinical limitations of specific tests and frequency of performing specific tests - is publicly available via the NWAFT Pathology Services website. The Hinchingbrooke Pathology User Guide is accessible via the 'Hinchingbrooke' tab on the same website.

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 professional judgement of specific results can be obtained by contacting the laboratory results enquiry lines on the following numbers, from where calls can be directed to the appropriate area:

PCH: 01733 678468
Hinchingbrooke: 01480 416151

Clinical staff are also available to assist users in obtaining 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. For advisory services please refer to the NWA Pathology website for contact details.

5.4 Structure & Authority

The legacy organisations 'Peterborough & Stamford Hospitals NHS Foundation Trust' and 'Hinchingbrooke Healthcare NHS Trust' merged in 2017 to form North West Anglia NHS Foundation Trust (NWAFT). NWAFT is registered as an NHS care provider under Monitor licence number 120083. Regulatory inspections of the Trust are conducted by the Care Quality Commission (CQC).

The Pathology Laboratories at Peterborough and Hinchingbrooke Hospitals and Phlebotomy service at Stamford & Rutland Hospital are a part of NWAFT's Family and integrated Support Services (FISS) division.

The management structure and relationships between management, technical and support services are demonstrated in the organisational charts document GEN-QP-0001D.

All non-medical staff are accountable to the Pathology Services Manager (PSM), through their Departmental Manager. Clinical scientist staff are accountable to the clinical head of department for clinical issues and managerially accountable to the PSM through their Departmental Manager.

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

Departmental Health & Safety Officers are responsible through their Departmental Manager to the Pathology Health & Safety Lead; who has ultimate responsibility for ensuring the Health, Safety and Welfare of staff and visitors within Pathology. The Pathology Health & Safety Lead is the Chair of the H&S Committee meetings (see documents GEN-TOR-H&SCommittee: *Terms of Reference – Pathology H&S Committee,* and GEN-QF-H&SAgenda: *Pathology Health and Safety Agenda*), through which departmental Health & Safety Officers will discuss and review issues relating to health and safety. The Pathology Health & Safety Lead is responsible for escalating issues relating to health and safety to the MGC.

Departmental IT Officers are responsible through their Departmental Manager to the Pathology IT Lead for issues relating to the LIMS and other Pathology-wide IT applications. The Pathology IT Lead is the Chair of the IT Forum meetings (see documents GEN-TOR-ITFORUM: *Terms of reference – IT forum*, and GEN-IT-Agenda: *IT Forum Agenda*), through which departmental IT Officers will discuss and review issues relating to IT. The Pathology IT Lead is responsible for escalating issues relating to IT to the MGC.

Departmental Quality Officers (QOs) are responsible through their Departmental Manager to the Pathology Quality Manager (PQM) for issues relating to quality and the maintenance of the QMS. The PQM is the Chair of the Quality Forum meetings (see documents GEN-TOR-QualityForum: *Terms of Reference – Pathology Quality Forum*, and GEN-QF-QualityforumTemp: *Pathology Quality Forum Template*), through which departmental Quality Officers will discuss and review issues relating to quality. The PQM is responsible for escalating issues relating to quality to the MGC.

Departmental Training Officers (TOs) are responsible through their Departmental Manager to the Pathology Training Lead; who has ultimate responsibility for ensuring compliance with National, Trust and departmental training requirements. The Pathology Training Lead is the Chair of the Education, Learning & Development (ELD) Forum meetings (see documents GEN-TOR-ELD: *Terms of Reference – Education & Training Group Forum*, and GEN-QF-TrainingAgenda: *Pathology Training forum agenda*), through which departmental Training Officers will discuss and review issues relating to staff training. The Pathology Training Lead is responsible for escalating issues relating to training to the MGC.

The main management committees within the Pathology service together with their remits are summarised within Appendix 3 of this Quality Manual (GEN-QP-0001E - *QM Appendix 3: Committees*).

Departments must nominate named deputies for each of the key leadership roles within the department. These will typically be selected from the pool of Specialist Biomedical Scientist (BMS6) staff within each department. In the absence of key leadership staff, the nominated deputy will fulfil the role of the absent member of staff.

Regular departmental staff meetings (GEN-QF-DeptMeetingTemp: *Pathology Departmental Meeting Template*) are held for each pathology discipline, and active participation by all staff is encouraged. These meetings offer opportunities for staff to suggest changes and quality improvements. Minutes of the meetings are taken, recorded on Q-Pulse, and distributed electronically to all relevant staff.

Various leadership meetings occur to ensure that there is suitable dialogue between Pathology and Trust management. The document GEN-EXT-FISSGOVSTRUC (*FISS Governance Structure*) details the division's leadership meeting structure.

The level of authority and responsibility that each individual staff member has in terms of the QMS is reflected in their Q-Pulse access permissions. These are documented in *Q-Pulse User Account Management & Access Privilege Levels* (GEN-QP-QPulseManage).

5.5 Objectives & Policies

The Pathology Department Management & Governance Committee has defined the following Quality Policy which meets the requirements of this International Standard and is appropriate to the purpose of this organisation.

The signed copy of the Quality Policy can additionally be found as an independent document, GEN-QP-0001A.

The NWAFT Pathology Department is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of our patients and users.

To ensure that these needs and requirements are met, the Department will:

- Conduct all activities in a such a way that the well-being, safety and rights of our patients are prioritised.
- Operate a quality management system to integrate the organisation, procedures, processes and resources.
- Commit to the development and implementation of the quality management system and continually improve its effectiveness and requirements for patients.

- 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.
- Notify the requester in the event of delay to an examination that could compromise patient care.
- Meet the needs and requirements of its patients and users.
- Provide examinations that fulfil their intended use and satisfy service user needs.
- 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. This includes the treatment of all patient samples or patients which will be treated with due care and respect at all times.
- Commit to the health, safety and welfare of all our 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, GDPR, NHS Information Governance and Caldicott Guidelines.

The Department will comply with standards set by The Blood Safety and Quality Regulations and The Human Tissue Authority. The Department at Peterborough City Hospital will comply with the standards set in BS EN ISO 15189. The Department at Hinchingbrooke Hospital will strive to meet the standards set in BS EN ISO 15189.

The Department is committed to:

- Staff recruitment, training, development, and retention at all levels to provide a full and effective service to our patients and users.
- The proper procurement and maintenance of such equipment and other resources that are needed for the provision of the service and to meet service user / patient needs.
- The collection, transport, and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations.
- 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.
- Producing continual quality improvement through the assessment of user and patient satisfaction; internal audit; external quality assessment; and the identification and mitigation of nonconformities and risks to patient care.

Signed by the Chair of Pathology Management & Governance Committee (MGC)

…… **Date**……

The Departmental Quality Objectives are defined and agreed in the Pathology Annual Management Review, they are reviewed quarterly. Departmental Quality Officers and managers have the latitude to agree their own, department-specific objectives, provided that they are consistent with the Quality Policy. They must ensure that they are measurable and are monitored. This then assures the integrity of the management system as changes are planned and implemented.

The Departmental Key Performance Indicators are defined and agreed in the same document, these are reviewed monthly.

5.6 Risk Management

A comprehensive risk assessment process is in place which considers risk to service provision and risks to patient care, as well as health and safety-associated risks. Any risks identified to be significant or high are recorded via the Trust Risk Register with regular updates presented to the Laboratory Director and higher Trust Leadership on any progress taken to mitigate these risks. Any audit findings found to pose a potential risk to patient safety and care are prioritised for urgent action to mitigate the risk. Any corrective or preventive actions are recorded within the CA/PA module of Q-Pulse.

6 Resource Requirements

6.1 General

The following headings describe the means through which the Department ensures the adequacy of the resources associated with its activities.

The CA/PA module of Q-Pulse is used to record any nonconformities that have a root cause associated with the availability or functioning of laboratory resources (see also Section 8.7).

Where corrective or preventive actions propose a change to laboratory resources, the change must be documented and authorised as per the SOP GEN-QP-CHANGECTRL: *Change Control Overview SOP*. This will ensure that resource changes are effectively and formally scrutinised by all parts of the organisation which are affected by the change.

6.2 Personnel

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) has its own designated Human Resources Business Partner and HR Advisor who provide support and advice on HR matters.

The Laboratory has documented the personnel qualifications required for each employment grade. These details are defined in the *Personnel Management* SOP, GEN-QP-PersonnelMgt. Registered Medical staff, Biomedical Scientists and Clinical Scientists are authorised signatories of clinical reports within their specialist areas of competence.

In accordance with the Trust's *Professional Clinical Registration Policy* (accessible via the Trust intranet), staff that are employed to grades where mandatory registration is required (e.g. registered Nurses, Doctors, Clinical Scientists and Biomedical Scientists) must provide documentary evidence of their registration 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, 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.

Staff are aware of their requirement to work impartially and ethically, and of the processes in place for identifying and reporting any threat to this requirement (see also Section 4.1 and 4.2).

Staff are aware of the Departmental Quality Policy, which entrenches the laboratory's commitment to meeting the needs and requirements of patients and users (see also Section 5.5).

Staff are aware that it is **their responsibility** to ensure their actions and conduct are consistent with the Departmental Quality Policy and the contents of this document. A deliberate or malicious failure to conform with these procedures and policies could be regarded as misconduct, which may lead to disciplinary action being taken against the personnel concerned.

In accordance with the Trust's *Induction Policy* (available via the intranet) it is a mandatory requirement that all non-medical new starters attend a Corporate Induction ('Welcome to Our Trust') and a local (departmental) induction. Medical staff must attend their own general medical induction organised through either the Junior Doctors' Induction Programme or by Medical Recruitment.

Corporate Induction sessions are run at the beginning of each month and new employees should attend the closest induction to their start date. This will be either at Peterborough City Hospital or at Hinchingbrooke Hospital. If there is any reason a new member of staff cannot attend Corporate Induction at the earliest opportunity after employment commences (e.g. sickness, compassionate leave) they must inform the Learning Centre who will book them on to the next available induction session.

The procedures for the local induction are described in the *Pathology Induction Manual*, GEN-TRN-001.

Effective local induction is the responsibility of the individual's Line Manager. The *Local Induction Checklist* (GEN-TRN-001a) contains a standardised set of essential information which all new starters need to receive as specified during their induction period. Some of the information will be explained by managers or other staff, whereas some of the information will be for the new employee to discover themselves through observation or research. On completion, the checklist should be signed, dated, and stored in their personal file. An initial development review should be carried out after three months in post to provide a standard check that induction has been satisfactorily completed and resolve any problems.

All laboratory areas operate a system of competency assessment to provide evidence that staff have the competence to perform the laboratory activities for which they are responsible. 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. Protocols for the completion, assessment and recording of competency are detailed in the *Pathology Training Policy*, GEN-TRN-POLICY.

The level of authorisation that an individual possesses to perform laboratory activities is dependent upon their staff grade, and by extension, their personal qualifications and Professional Registration status. Laboratory competency documents specify which tasks are applicable to each staff grade. IT permissions (WinPath Enterprise, middleware and Q-Pulse access levels) ensure that personnel are restricted to laboratory activities applicable to their staff grade.

The Trust requires that all staff participate in mandatory training for elements including (but not restricted to) information governance & data security; fire safety; safeguarding; and equality, diversity & human rights. Some elements require competency renewal on an annual or triennial basis. Staff are aware that **they are responsible** for their participation in continuing education and regular professional development. The laboratory provides programmes of on-going professional development that all staff are given the opportunity to attend. A review of the effectiveness of these programmes is considered within the departmental management reviews.

Employee personal information, and documents such as job descriptions and contracts, are stored in Personnel Files held by the Departmental Administrators. All staff have the right to examine records of data kept by the Trust that refer to them. Records of laboratory training and competence are maintained using the *People*

module of Q-Pulse, as per SOP GEN-TRN-Pathology training records on Q-Pulse. Records of participation in Trust mandatory training are maintained by the Workforce Information department, which produces monthly Statutory and Mandatory Training Compliance Reports for Departmental Managers and Training Officers. Staff can access their personal mandatory training record via the 'My Compliance' module of the NHS Electronic Staff Record (ESR).

Laboratory management operates both an informal and formal responsive approach to addressing staff needs and performance. Staff can freely discuss their needs with senior laboratory staff on a day-to-day basis or via a 1 to 1. This system is effective in dealing with immediate needs, and is supported by the Trust's formal *appraisal process*. The Appraisal process, as defined on the Trust intranet, is designed to:

- Enable individuals to reflect on their experience in the last year and discuss what support they need now and going forward.
- Enable line managers to appreciate and celebrate their employees experience and gain insight into what might be needed for them in the short term and the year ahead.
- Discuss priorities for the job role and support for development/training as appropriate for the individual.

6.3 Facilities & Environmental Conditions

The laboratories are organised to provide an appropriate working environment that complies with relevant Health and Safety legislation. All laboratory areas receive conditioned air as provided by the Hospital Building Management System to facilitate the correct operation of analysers. The facilities have been designed to ensure provision of adequate lighting, power supply (including contingency), ventilation, water supply, waste disposal, staff communication systems (via Voice over Internet Provider phone systems and NHS email), and safety systems (including - but not restricted to – fire detection, emergency release door systems, emergency showers and eyewash facilities).

The upkeep and repair of laboratory premises at PCH is the responsibility of the Trust's maintenance provider, Brookfield-Multiplex. The upkeep and repair of laboratory premises at Hinchingbrooke Hospital is the responsibility of the Hospital Estates and Facilities Department.

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

Access to non-public areas at PCH is controlled by swipe card access doors. All departmental staff, as well as the designated cleaning, portering and maintenance staff are permitted access to the PCH Pathology laboratory. The Containment Level 3 Suite in the Microbiology laboratory is a specialist area of work with further access restrictions (see SOP MIC-LP-B026: *Category 3 Suite*).

All other personnel (including visiting maintenance personnel and other visitors to the department) are only allowed access following approval, and are not to 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 can expect to 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.

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

The entrance to the Phlebotomy Suite at Stamford and Rutland Hospital is kept locked at all times when staff are not in attendance.

Only departmental staff have access to the laboratory areas at Hinchingbrooke Hospital, 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 to the Hinchingbrooke laboratory 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 can expect to be challenged by a member of staff to determine the reason for their presence.

Visiting Maintenance Personnel must report to the Hinchingbrooke Hospital Estates and Facilities Department and obtain permission to work, prior to undertaking any work within the laboratory.

The Hinchingbrooke Body Store has swipe card access for Bereavement and Mortuary staff, and nominated porters. A doorbell is provided for others to request attention or 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-controlled laboratory, in a key cupboard.

The Departmental 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) in conjunction with the Institute of Biomedical Science (IBMS). This document is stored in Q-Pulse as GEN-EXT-001. Storage facilities comply with Caldicott Principles, Information Governance and the Data Protection Act. Document storage instructions are provided in SOP GEN-QP-QARECS: *Control of process and quality records*.

The storage of clinical samples is always kept separate from those materials used in testing to reduce the possibility of cross-contamination. The 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 hospital 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 Facilities Management 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 clinical samples, kits and reagents
- -20°C and -80°C storage for samples, cultures, and reagents
- 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 MHRA regulation for this material.
- Reagents, calibrators, and quality control material are stored in appropriate conditions according to instructions.

All refrigerators, freezers and laboratory storage areas are temperature monitored using the Checkit Connected Automated Monitoring system, with records retained as per SOP GEN-QP-QARECS. Where the data temperature monitoring data is out of specification and may impact the quality of the service provided, a nonconformity should be raised using the Q-Pulse CA/PA module (see also Section 8.7).

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-site. The laboratory provides staff with:

- Areas for hanging laboratory coats.
- Storage area for clean laboratory coats.
- Lockers to store personal belongings.
- Hand wash basin facilities.
- Shower facilities.
- A seminar room for meetings/seminars (PCH), additional meeting rooms across the Trust are available for booking via cloudbooking system
- Quiet areas for interviews and study.

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

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

There is full patient access to Phlebotomy services at Stamford and Rutland Hospital and Hinchingbrooke Hospital, including disabled access. The waiting area is separate from the Phlebotomy Room where samples are procured. Within the Phlebotomy Room, each station is segregated so that patients are afforded suitable privacy. Access to toilet facilities and to emergency first-aid, if required, is provided via the Outpatients Departments which are situated very close to the Phlebotomy facilities.

6.4 Equipment

The selection and purchase of laboratory equipment is governed by the *Procurement of Pathology Equipment* SOP, 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 are renewed prior to their 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 ongoing software and hardware safety enhancements and, at year 5, to discuss technology upgrades or refreshment.

Pathology staff are only permitted to use a particular item of equipment unsupervised when an appropriate member of their leadership team has established that they are competent to do so. This same restriction applies to staff operating POCT devices outside of the laboratory's immediate control. Competence is documented in the individual's training record (see also Section 6.2).

Individual equipment is uniquely labelled with the supplier's serial number so that each can be definitively identified. An inventory of capital /MES equipment is held within the Assets Module of Q-Pulse.

Before new electrical equipment is put into routine use it must be electrical safety tested by Ergea or Brookfield-Multiplex at PCH, or the Technical Services or Estates and Facilities Department at Hinchingbrooke Hospital, as per Trust requirements. The equipment will then undergo checking to verify that it is conforming to acceptability criteria in accordance with the *Validation & Verification in Pathology* SOP (Q-Pulse: NWA GEN-QP-Validation&Verification in Pathology). This document specifies the verification process for unmodified methods/assays which have already been validated by the manufacturer, and the full laboratory validation process for in-

house or modified procedures. Individual laboratory departments have more detailed procedures covering this requirement. The records of equipment verification are kept within individual departmental records or in the Assets Module of Q-Pulse (see also Section 7.3)

Manufacturer equipment operation manuals are held within laboratory departments (hard copies), or the Q-pulse Assets register (electronic copies).

The level of authority and responsibility each staff member has in terms of their ability to adjust laboratory equipment is reflected in their access permissions and privileges. All staff are aware that the adjustment of laboratory equipment is only to be performed by authorised personnel, and that unauthorised adjustment may invalidate both the equipment warranty and examination results.

After installation of new equipment, full operator training is conducted either on site, at the instrument manufacturer's premises, or at another laboratory. All new instruments must have a minimum of a one-year parts and labour warranty. After this initial period, the department will either negotiate a service contract for preventive maintenance with an approved provider, or a preventive maintenance programme will be included in the MES agreement.

Any item of equipment that suffers damage, which shows signs of malfunction, or that is shown by calibration or otherwise to be defective and unfit for use is immediately withdrawn from service and labelled accordingly. Checks are made to assess if the defective equipment had any impact upon examination results reported prior to the defect being discovered. If so, suitable remedial and corrective actions are undertaken. In the event of an equipment defect, alternative arrangements must be made until the item has been repaired, re-calibrated and verified for use. Any such actions are recorded in Assets module of Q-Pulse.

An Equipment Decontamination Certificate (GEN-LF-Decon in Q-Pulse) must be completed prior to an engineer commencing work on any equipment.

Adverse incidents and accidents associated with the use of equipment are recorded as nonconformities using the CA/PA module of Q-Pulse. These are reviewed annually using the Suppliers module of Q-Pulse. In addition, any equipment failures which have resulted in the generation of incorrect results will be logged via the Trust Datix adverse event reporting system. The equipment supplier must be notified of any serious equipment failure, or trends that indicate equipment defects. The MHRA and/or HSE must also be notified when necessary.

Equipment records are kept within individual departments (hard copies) or on the Assets module of Q-Pulse (electronic copies). As a minimum these records detail the following:

- Identity of the equipment.
- The manufacturer's name, model and serial number, or another unique identifier.
- Contact information for the equipment supplier.

- Date of receipt into the laboratory, acceptance testing, and the date the equipment entered use.
- Details of where the equipment is located within the laboratory.
- Equipment condition when received, i.e. new, used, or reconditioned.
- Manufacturer's instructions.
- A maintenance record, including any preventative maintenance performed.
- Record of any damage, malfunction, modification, or repair.
- Performance records that confirm the equipment's ongoing acceptability for use e.g. calibration/re-calibration records, verification/re-verification records.
- Status of the equipment (e.g. active, out-of-service, quarantined, obsolete).

6.5 Equipment Calibration & Metrological Traceability

Individual laboratory departments have procedures for the calibration of equipment to ensure the reproducibility and consistent reporting of examination results. For quantitative methods, these procedures must include a record of metrological traceability.

Laboratory calibration procedures must consider the following:

- The conditions of use and the manufacturer's instructions.
- Evidence of metrological traceability.
- The verification of the required measurement accuracy, and the functioning of the measuring system at defined intervals.
- A record of the equipment's current calibration status, and date or re-calibration.
- Where correction factors are applied as a result of calibration, all previous calibration factors are suitably updated.
- The management of calibration failure to minimise the risk to service provision and patient care.

Where equipment calibration is outsourced to an external agency, only contractors that are accredited to BS EN ISO 17025 should be selected to perform this function.

The measurement uncertainty must be calculated for all laboratory quantitative methods, using relevant recorded calibration data. Quantitative results must be traceable to the highest metrological order available, and to the International System of Units (SI).

Information relating to metrological traceability is typically provided by the manufacturer of system calibrators. This information is only valid whilst the examination systems and calibration procedures are used as specified by the manufacturer, i.e. without in-house modification. Only manufacturers of reference material that are accredited to BS EN ISO 17034 should be selected as suppliers of calibration material. For genetic examinations, traceability to genetic reference sequences must be documented. If it is not possible to provide evidence of metrological traceability, the laboratory will formally document its acceptance of the method in terms of producing results that are fit for purpose and confirmed by suitable comparison studies.

For qualitative laboratory methods, traceability may be demonstrated by recording the results obtained from the testing of known reference material or the repeat testing of previous samples. This record must demonstrate consistency in identification and/or intensity of reaction.

6.6 Reagents & Consumables

The selection and purchase of laboratory services and supplies is governed by SOP GEN-MP-SuppliesProcure - *Procurement of services and supplies.* 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.

The laboratory will use outside services and supplies of adequate quality to sustain confidence in the laboratory's test results. All commercially sourced goods, kits and reagents should be European Conformity (CE) marked or UK Conformity Assessed (UKCA) wherever possible. Where no independent assurance of the quality of support services or supplies is available, validatory checks, calibrations or other actions shall be performed; to ensure and document that the purchased goods meet the requirements of the laboratory.

Reagents and consumables are stored according to manufactures' instructions and the details of batch numbers (where present) are recorded. Laboratory handling and storage precautions are evaluated using COSHH documentation in conjunction with local risk assessments. All refrigerators, freezers and laboratory storage areas are temperature monitored using the Checkit Connected Automated Monitoring system (see also Section 6.3). On major instrumentation platforms, on-board systems monitor the temperature data for reagents automatically with alarms /alerts in place for excursions.

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. The same verification approach is applied to changes in consumables that may affect the quality of examination results. Each laboratory department is responsible for maintaining its own system for the pre-acceptance testing of reagents and consumables.

Each laboratory department uses 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. Reagents and consumables should only be used as instructed. Methods for the use of reagents and consumables in the form of manufacturer's instructions and local technical SOPs are available either in each laboratory department (hard copies) or in the Q-Pulse Documents module (electronic copies).

Adverse incidents and accidents associated with the use of specific reagents or consumables are recorded as nonconformities using the CA/PA module of Q-Pulse.

These are reviewed annually using the Suppliers module of Q-Pulse. In addition, any reagent or consumable nonconformities which have resulted in the generation of incorrect results will be logged via the Trust Datix adverse event reporting system. The relevant supplier must be notified of any serious quality issue relating to reagents and/or consumables, or trends that indicate persistent quality issues relating to reagents and/or consumables. The MHRA and/or HSE must also be notified when 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:

- Name of the reagent or consumable.
- Manufacturer's details including name, instructions and batch code or lot number.
- Condition upon receipt (e.g. acceptable, damaged).
- Dates of receipt, expiry and first use, as well as the date the material was taken out of service (when applicable).
- Records that confirm the reagent's or consumable's initial and ongoing acceptance for use.
- If the reagent is prepared, resuspended, or combined in-house: the name of the person who performed the preparation, date of preparation and date of expiry.

6.7 Service Agreements

The procedure for the establishment and review of service agreements for providing laboratory activities is defined in SOP GEN-MP-SLA: *Service Agreement (SLA) Procedure.* This document is produced in accordance with the Trust's *Contracting Policy* (accessible via the Trust intranet). Service Level Agreements (SLAs) produced by the laboratory must define the objectives of the service and the requirements of the user, as well as the capacity of the laboratory to meet these requirements in terms of procedures, resources and training requirements. The laboratory clearly defines the location from which services will be delivered. Where a Pathology service is provided outside of the laboratory (i.e. using point of care testing), the responsibilities and authorities of both the laboratory and POCT operators must be clearly defined and communicated.

SLAs are reviewed at monthly MGC meetings and in the Annual Management Review (AMR). Contract reviews are performed as part of the AMR including analysis of user complaints and the outcomes of user surveys.

6.8 Externally Provided Products & Services

The general requirements for sample referral to reference laboratories are described in the *Referral to other laboratories* SOP (Q-pulse: GEN-QP-Referral). This document is supplemented by more detailed departmental methods.
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.

Wherever possible, samples are referred only to laboratories that are BS EN ISO 15189 accredited. Ideally, referral laboratories which are not accredited will be working towards BS EN ISO 15189 accredited status. The performance, accreditation status and selection of referral centres is reviewed annually; using the Suppliers module of Q-Pulse. Where the referral laboratory is not listed as 'Accredited', they are requested to produce documentary evidence to prove their continued suitable performance in inter-laboratory comparison programmes, staff competency, and evidence of meeting the stated turnaround times for the assay(s) being undertaken. This evidence is recorded in the 'Suppliers' module of Q-Pulse.

The NWAFT Pathology Department retains responsibility for ensuring that the results of tests undertaken by referral laboratories are provided to the test requester. Results generated by a third-party referral centre or Consultant must be clearly identified and referenced as such.

A list of referral centres and facilities currently in use is available as an appendix of this quality manual (Appendix 4, GEN-QP-0001B), and is accessible via the Documents Module of Q-Pulse.

The laboratory ensures that external calibration services (e.g. pipette calibration, calliper calibration, thermometer calibration) are provided by contractors that are BS EN ISO 17025 accredited. The performance and accreditation status of calibration providers is reviewed annually, using the Suppliers module of Q-Pulse.

Other externally provided services (e.g. specimen transport services, equipment maintenance services, external quality assurance programmes) are selected in accordance with the Trust's *Contracting Policy*. Specimen transport services must be selected that meet the UK Government *Packaging and transport requirements for patient samples,* Packaging Instruction P650, and transport of Biological Substances standard UN3373. External quality assurance providers must be accredited to ISO/IEC 17043. The performance of all external service providers against the requirements of the laboratory and ISO 15189 is evaluated using the Audit and Suppliers modules of Q-Pulse.

In all instances, specific issues relating to the performance of external providers can be raised and discussed at MGC meetings, and in the Pathology Annual Management Review.

7 Process Requirements

7.1 General

A comprehensive risk assessment process is in place which considers risk to patient care and service provision in relation to laboratory processes, as well as to health and safety-associated risks. Any identified risks to patient care or service provision are logged on the Trust Risk Register using the Datix software (see SOP GEN-QP-Riskregister: *Pathology Risk Management and Register*). Regular updates are provided to Trust Management on any progress taken to mitigate these risks that have been classified as significant or high. Any residual risk should be communicated to service users, if appropriate. Any nonconformities that occur in the laboratory which have a potential impact on patient safety are prioritised for urgent action to mitigate the risk. The CA/PA module of Q-Pulse is used to record any nonconformities associated with the availability or functioning of laboratory processes (see also Section 8.7).

Where corrective or preventive actions propose a change to laboratory processes, the change must be documented and authorised as per the SOP GEN-QP-CHANGECTRL: *Change Control Overview SOP*. This will ensure that process changes are effectively and formally scrutinised by all parts of the organisation which are affected by the change.

The monitoring and evaluation of risks is performed through MGC meetings and the 'Follow Up' component of the Q-Pulse CA/PA module.

Opportunities to improve patient care are identified through a number of methods (see also Section 8.5).

7.2 Pre-Examination Processes

Procedures for PCH general laboratory pre-examination activities are detailed in the *Specimen Reception* SOP, SR-LP-017 Specimen Reception. Further, department-specific pre-examination protocols can be found in the relevant departmental SOPs. These are accessible via Q-Pulse.

Pre-examination information is available to patients and users via the NWAFT Pathology Services website. This information includes:

- The locations of the laboratories, their opening hours and key contact information.
- The procedures for the requesting and collection of samples.
- The scope of laboratory service provided and expected result turnaround times, including for examinations referred to other laboratories.
- The availability of advisory services.
- Requirements for patient consent.
- Factors known to significantly affect the performance of the examination or the interpretation of the results, including the impact of deviations from the specified procedures for the requesting and collection of samples.

- The Trust complaints procedure.

The laboratory request that is completed either electronically via the Sunquest Integrated Care Environment (ICE) system or manually using a hand-written request form is regarded as a contractual agreement between the laboratory and its users. Request forms (both electronic and manual) are designed to ensure:

- Traceability of the patient to the request and sample (i.e. full name, date of birth and unique identifier [NWAFT DIS number or NHS number]).
- That examinations are requested unambiguously.
- The identity of the user and their contact information is provided, should the laboratory need to clarify the user's request.
- That clinical information relevant to sample collection, examination performance or result interpretation is provided (e.g. fasting status, date/time of drugs administered).
- That informed technical and clinical advice can be provided to the user.

Additionally, urgent and add-on requests can be requested verbally, but it is an expectation that the user will confirm such requirements with an electronic ICE request.

Information and instructions for pre-collection activities are provided in the *Specimen Information* section of the NWAFT Pathology Services website, and within the specific departmental sections of the Hinchingbrooke Pathology User guide (accessible via the same website). The information includes instructions on the processes to be followed prior to and during sample collection including:

- The laboratory's specimen acceptance criteria, including labelling requirements.
- The preparation of the patient (i.e. instructions for carers, sample collectors and/or patients).
- That suitable checks are made to establish and confirm the identity of the patient.
- The identity of the correct sample container and requirements for storage of sample containers prior to use.
- The volume of primary sample required, and the relevant collection order if multiple volumes are to be obtained.
- Recording the identity of the person collecting the sample, and the specimen collection date and time.
- The separation or division of the sample, if required.
- The correct storage of samples prior to specimen transport.
- The safe disposal of materials used during the sample collection process.

Information and instructions for obtaining patient consent are provided on the NWAFT Pathology Services website. For most routine laboratory procedures, consent can be inferred when a patient willingly submits to a sample collecting procedure (e.g. venepuncture). Users are made aware that high risk or invasive procedures may require special, recorded consent. Where obtaining consent is not

possible in emergency circumstances, the laboratory retains the right to carry out procedures that are deemed to be in the patient's best interest.

Instructions and guidance for sample transportation are provided in the *Transportation* section of the Pathology Services User Information web pages, and Hinchingbrooke Pathology User guide. Copies of this document have been provided to the managers of the NWAFT portering team, and to external couriers who are contracted to transport pathology samples between Trust sites and community GP surgeries. Additional copies are provided to the external courier services responsible for specimen transport to referral facilities at Cambridge University Hospitals.

All pathology samples being transported by road are sealed in compliance with P650 and UN3373 requirements. Correct packaging of samples is a requirement to mitigate the health risks that might be associated with breaches of sample integrity. The laboratory has a duty to notify the relevant sample transport providers where breaches of specimen integrity occur that might result in a risk to health.

All off-site service users receive at least two sample collections per day: usually towards the end of the morning and afternoon, to ensure that the integrity of the samples is not impaired due to prolonged storage following procurement. Where the quantity of samples procured at any one site is very large, additional sample collections are provided.

The performance of sample transportation systems is evaluated using the Audit and Suppliers modules of Q-Pulse, and through the Annual Management Review process.

In terms of sample receipt, the NWAFT Pathology Services website details the criteria required for samples to be accepted for testing by the laboratory. Departmental SOPs detail what actions are to be taken for those samples that are rejected for testing. All sample requests are date and time stamped upon receipt within the laboratory. It is a requirement of the LIMS system that the date and time of specimen receipt be logged, with the identity of the person receiving the sample being recorded via the LIMS audit trail. 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 a disclaimer indicating the nature of the problem and advising that necessary caution must be taken when interpreting the results.

Instructions for the handling and receipt of specimens marked as urgent are provided in the *Specimen Reception* SOP (SR-LP-017 Specimen Reception). LIMS-generated bar codes with 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.

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 the requesting of additional examinations on the same sample are provided to users on the NWAFT Pathology Services website. Where an examination is sensitive to sample stability, limits on the time between sample collection and examination are also stated on this website.

7.3 Examination Processes

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

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

When selecting examination procedures, preference is given based upon:

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

Electronic master copies of all examination process SOPs are held on Q-Pulse. The issue of controlled hard copies is performed only as per the 'Distribution of copies' component of each SOP. Laboratory protocols are reviewed and updated regularly by senior laboratory staff, and distributed electronically to all relevant personnel. Staff on the electronic distribution list are required to electronically acknowledge that they are aware of, and have read the contents of, the document. Electronic copies of manufacturers kit inserts are also held on Q-Pulse, and updated periodically. It is a requirement that all personnel, including POCT operators, are familiar with the contents of any relevant SOP and kit insert before performing an examination process, and that records are retained of which individuals were responsible for performing each examination process. Where bench-level abbreviated documents (work instructions, flow process diagrams, etc) are in use, these shall be subject to document control and correspond accurately to the protocol as described in the 'parent' SOP.

The continued appropriateness of examination processes is reviewed in departmental Leadership meetings, MGC meetings and the Annual Management Review.

Where examination procedures are being used without deviation from the manufacturer's requirements then the laboratory will independently verify the manufacturer's validation performance characteristics prior to introducing the

procedure into routine use. Where methods are revised by the manufacturer, the laboratory shall repeat the verification.

The laboratory will extensively validate an examination procedure to ensure that it is appropriate for its intended use where any of the following criteria apply:

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

Validated modifications to established examination procedures must be communicated to service users.

For both verification and validation of new methods; the laboratory will keep extensive records of the testing procedures employed, performance specifications achieved, results obtained, and evidence of suitable review and acceptance of the data generated. This must be accompanied by the correct change control documentation, as per the SOP GEN-QP-CHANGECTRL: *Change Control Overview SOP*. Historically, these records have been retained in individual departments. More recent verification and validation documentation is stored in either the Q-Pulse 'Documents' module (manual methods) or 'Assets' module (automated methods).

Detailed instructions for process verification and validation are contained in the *Validation & Verification in Pathology SOP* (NWA GEN-QP-Validation&Verification in Pathology), with discipline-specific guidance held in departmental SOPs.

For all processes with measured quantity values, the laboratory will determine the measurement uncertainty (MU) for the procedure. This includes qualitative assays that produce quantitative output data that is interpreted as positive or negative, based on a threshold. For such examinations, IQC data should be maintained that demonstrates the quantitative data obtained for the control material. The calculated MU will be documented and compared with manufacturer specifications, and be regularly reviewed. The laboratory will aim to minimise the impact of MU wherever possible. For assays where MU calculation is not possible or not relevant, the rationale for the exclusion of MU calculation shall be documented. The laboratory's estimates of measurement uncertainty can be made available to service users upon direct request to the Pathology Quality Manager, and should consider other sources of potential uncertainty.

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

Wherever applicable, biological reference intervals have been calculated for examination procedures and made available to service users via the *Specimen Information* section of the NWAFT Pathology Services website. Biological reference intervals provided by the manufacturer are to be used by the laboratory, except in situations where departmental Clinical Leads deem the manufacturer's reference intervals to be inappropriate for the population served.

Biological reference intervals should be periodically reviewed by laboratory personnel in liaison with the departmental Clinical Lead with respect to:

- Appropriateness to the population served.
- Any changes in pre-examination procedures.
- Any changes in examination procedures.

Amendments made to reference intervals must be communicated to the service user.

The laboratory aims to ensure the quality of its examinations by performing them under suitably controlled conditions. A comprehensive quality control approach is taken to pre-examination, examination, and post-examination processes. Quality control data must be recorded in a manner that monitors shifts and trends in assay behaviour, using statistical analysis where possible. This analysis should include the monitoring of lot-to-lot reagent or calibrator variation. Lot changes of internal quality control (IQC) material should be avoided on the same run as lot changes of either reagents or calibrators. Quality control data will be reviewed and signed off by an appropriate member of staff on a daily basis.

The laboratory aims to select, wherever possible, quality control materials that will react in a manner as close as possible to patient samples and present a clinically relevant challenge to the examination method. This applies to both IQC and external quality assurance (EQA) materials. QC materials and data are periodically reviewed to ensure that they continue to offer a reliable indicator of examination performance, and thereby minimise the risk of erroneous patient results. Any QC data trends that might indicate deterioration in the performance of an examination procedure must be logged as nonconformities using the CA/PA module of Q-Pulse (see also Section 8.7). Wherever possible, independently sourced third-party QC materials are used to reduce the possibility of bias associated with the use of reagents supplied by the system manufacturer.

Where appropriate IQC material is not available, the laboratory should employ alternative methods for IQC, such as the repeat testing of retained patient samples.

Further details of each laboratory's Quality Assurance programme can be found in departmental SOPs, accessible via Q-Pulse. These include procedures to prevent the release of patient results following QC failure, and the actions to take regarding the re-examination of patient samples following QC rule violations, including the need to review results obtained for samples that have been examined since the last successful QC test.

The laboratory enrols in third-party EQA schemes relevant to its testing repertoire, including POCT examinations. Wherever possible, preference is given to EQA schemes that have been assessed against ISO/IEC 17043; or those meeting the *Guidelines for the Requirements for the Competence of Providers of Proficiency testing Schemes*, as published by the International Laboratory Accreditation Cooperation (ILAC). When enrolling in an EQA scheme, the laboratory should review how the EQA target values are determined.

Where formal inter-laboratory comparison schemes are not available, the laboratory aims to use alternative methods to demonstrate the performance of its examination methods. These will be documented to include the rationale for the selected alternative in accordance with UKAS document TPS 47 (*UKAS policy on participation in proficiency testing*). Alternative methods might include the use of certified reference material, re-assessment of samples previously examined and exchange of samples with other laboratories.

EQA results are either displayed on departmental Quality notice boards in numerical and graphical format, or recorded on Q-Pulse and distributed to all relevant staff. Results are reviewed and discussed at departmental staff meetings. The Pathology Quality Forum is informed via departmental reports of any EQA-related issues.

Any inter-laboratory poor performance is recorded as a nonconformity in the CA/PA Module of Q-Pulse. Where a nonconformity is deemed to have a clinical impact, the investigation and corrective action must include a review of patient results that could have been affected, and service users informed accordingly.

Details of the quality assurance schemes to which the laboratory is currently enrolled are available as an appendix of the quality manual (GEN-QP-0001G, *QM Appendix 6: QA schemes*), accessible via the Documents Module of Q-Pulse.

The laboratory's use of IQC material and EQA enrolment is consistent across sites, to permit the comparison of examination results obtained using different equipment/methods and/or at different locations.

7.4 Post-Examination Processes

The laboratory's report format is designed to present results clearly, unambiguously and in accordance with manufacturer's instructions. Reports contain sufficient information (e.g. reference ranges, clinical interpretative comments, guidance for when special counselling should be provided for the patient, comments on discrepancies that may occur as a result of testing using different procedures or at different locations) to permit the user to understand the results and their significance. Reports are generally issued electronically, though some users require additional hard-copy versions of reports. Hard-copy reports are printed and distributed via the internal post systems.

An authorised member of staff reviews significant results before they are released. The level of authority required to release results is defined and agreed by departmental Clinical Leads, with mechanisms built into the LIMS to prevent the release of results by unauthorised personnel. The LIMS audit trail documents which laboratory personnel were responsible for the review and release of a result. No results should be released unless they have been evaluated against IQC data and patient history, where applicable. After IQC check, certain results that meet approved, predetermined selection criteria are released electronically without manual intervention by laboratory personnel. Departmental SOPs provide more detail relating

to the specific reporting requirements for each examination procedure, as well as protocols relating to the automated selection, review, and release of results.

If a result falls within established alert or critical decision values, departmental SOPs contain the escalation protocols for notifying either the user or departmental clinical staff as soon as is relevant. The LIMS audit trail permits the recording of the results conveyed, the recipient, the time and date of the communication, and any difficulties encountered in notification. Results issued in this way must be followed by an electronic/hard-copy report.

Laboratory reports are formulated to include at least the following data items. If any of the below information is omitted from the report, the laboratory shall document the reason for this:

- Patient identification on each page of the report.
- Date (and time, where relevant) of specimen collection on each page of the report.
- Date (and time, where relevant) of report issue on each page of the report.
- Name of the laboratory issuing the report.
- Identification of the requester and the requester's location.
- The type of primary sample received.
- Unambiguous identification of the examination(s) performed.
- The examination procedure used (if appropriate).
- Examination results and units of measurement, reported in SI units or units traceable to SI units, where applicable.
- Biological reference intervals or clinical decision limits (where appropriate).
- Identification of any examinations performed as part of a research and development programme, for which no specific data on assay performance is available.
- Identification of the person reviewing the results and authorising the report (if this is not present on the final report it can be requested from the audit trail held on LIMS if required).
- Identification of any results which are to be regarded as preliminary.
- Identification of any critical results.
- Identification of any tests undertaken by a referral laboratory and the name of the referral laboratory performing the examination.
- Any interpretative, cautionary, or explanatory notes.
- Page number to total number of pages (i.e. Page 1 of 5, etc).

Periodic audits are undertaken to check the accuracy of results that are manually transcribed, and that patient results issued electronically are accurately reproduced by IT systems external to the LIMS.

In circumstances where it is found to be necessary to issue a supplementary report, a new test report is generated in accordance with the departmental SOPs. This revised report will refer to the date and patient identity of 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, and the reason(s) for this. 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 a log of the original version of the report, which can be subsequently accessed by those with suitable access rights if required.

Where the report amendment has an impact upon patient care, the Trust Datix system should be used to log the nonconformity. Records of all amended results should be recorded as nonconformities in the CA/PA Module of Q-Pulse, as per Section 8.7).

The post-examination handling of samples is described in SOP GEN-QP-ClnMtrl: *Control of clinical material.* This procedure states how samples are indexed, stored, and disposed of in accordance with regulations and national guidance. Further, discipline-specific, detail is provided in departmental SOPs.

7.5 Nonconforming Work

When any aspect of laboratory activities does not conform to its own procedures, quality specifications or user requirements, protocols are established for the recording of these nonconformities using the CA/PA module of Q-Pulse and/or the Trust's Adverse Event Reporting (Datix) software. These protocols can be found in the following SOPs:

- GEN-QP-EvalQA: *Evaluation & Quality Assurance.*
- GEN-QP-QImprovement: *Quality Improvement.*
- GEN-QP-QPULSECAPA: *Q-Pulse CAPA.*
- GEN-QP-DATIX: *Trust adverse event reporting via Datix.*

These documents detail the laboratory processes for reviewing the extent of nonconformities, and taking and recording corrective or preventive actions to mitigate occurrence/re-occurrence. These actions must focus on reducing the risk of harm to patients and be proportional to the risk of occurrence/re-occurrence. The responsibilities and authorities for the management of nonconformities are specified, including those in relation to the following (where they are applicable):

- The acceptability of the nonconforming work.
- The halting and re-commencement of testing, and withholding of patient reports during any investigation process.
- Analysis of examination results that were released prior to the identification of the nonconformity.
- The notification of the nonconformity to service users, and amendment of results.

7.6 Control of Data & Information Management

The Pathology Department has access to the patient data and information necessary to perform its activities via the Clinisys WinPath Enterprise system (WPE). 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. The management of the WinPath Enterprise information system is provided by Clinisys with the support of the departmental IT Lead (see also Section 4.2). The legally binding agreement for the management of the LIMS can be accessed via the Documents module of Q-Pulse (GEN-MF-SLA-Winpath).

The LIMS (WPE) has been robustly validated for use within the laboratory. Any upgrades to the system software are thoroughly verified and approved for use prior to introduction through the formal change control record, 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 Assets module of Q-Pulse. WPE User Manuals are also accessible via the Assets module of Q-Pulse.

Security access to WPE and the Trust network is strictly controlled via the Trust IT department security procedures, and subsequently via security access control for individual users. The systems prompt changes in Passwords at regular intervals to maintain security.

The WPE LIMS is operated in an environment that complies with Clinisys specifications. The laboratory areas in which WinPath terminals are located are temperature monitored using the Checkit Connected Automated Monitoring system, with records retained as per SOP GEN-QP-QARECS (*Control of process and quality records*).

Operational elements of system maintenance are undertaken by Clinisys in accordance with the service agreement GEN-MF-SLA-WinPath (*SLA-Clinisys*). Electronic data is backed up in accordance with this SLA. The recording of system failures and remedial and corrective actions is done through the Assets module of Q-Pulse.

In the event of a protracted LIMS or electrical failure then the *Pathology Business Continuity Plan* (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.

7.7 Complaints

Complaints are managed centrally by the Trust Complaints Department. They are disseminated via General Managers for departmental investigation.

Pathology staff receiving verbal complaints should endeavour to resolve them on the spot; rapidly and in an informal and sensitive manner, apologising if necessary. If they are unable to do so or the complainant remains unsatisfied, then they must refer the complaint to a senior member of Pathology staff. If the complainant remains dissatisfied, the senior member of staff should advise the complainant of how to make a formal complaint.

Where a patient or service user wishes to make a formal complaint, the complaint may be made verbally or in writing (including electronically). If the complainant wishes to make a verbal complaint a time will be arranged for a member of the complaints team to speak with the complainant taking a written statement of the concerns being raised. See the Trust Complaints policy for details on how to contact the complaints team or print off a copy of Making a Formal Complaint from the Trust intranet page for additional information.

Where an employee has a work-related complaint, this should be raised in the first instance with their line manager. Most issues will be resolved by having an informal and constructive discussion. If the employee does not feel comfortable discussing the issue with their line manager, alternative routes of escalation include (but are not restricted to):

- Pathology Service Manager or Deputy Service Manager.
- Trust Freedom to Speak Up Guardian.
- Trust Human Resources Department.
- Trade Union Representatives.

The Trust procedure for a staff member wishing to make a formal complaint is covered in the *Resolution Policy*, accessible via the intranet.

The laboratory investigates all complaints received from patients, service users and staff. The full procedure for this is detailed in SOP GEN-QP-Complaints: *Complaints and Feedback*. This includes the protocols for acknowledging receipt, substantiating, investigating, and resolving the complaint; and providing the complainant with the outcome. It is the responsibility of departmental managers to ensure that actions taken to resolve a complaint are non-discriminatory, appropriate and proportional. Complaints are deemed to be sensitive information and full records of complaints are not therefore stored in Q-Pulse. Instead, details of complaints are stored in an access-restricted file on the A: drive of the trust server. Complaints are reviewed by Pathology managers at MGC meetings and through the Annual Management Review. Formal complaint responses are checked and approved by the Divisional Complaints Team to ensure impartiality.

7.8 Continuity & Emergency Preparedness Planning

The department is required to ensure that it can respond appropriately and minimise any disruption following any incident which compromises, or threatens to compromise, its ability to provide services as normal. Protocols for continuity and emergency preparedness are detailed in the *Business Continuity Plan* (document GEN-MP-BsCnPln). This document provides action plans for dealing with emergency situations which have been identified through risk assessment as presenting a risk to the continued operation of the laboratory. Action plans incorporate the roles required to execute the plan (including command roles), and the responsibilities and actions attached to each role. Information and training are provided to relevant personnel, where required (e.g. first aid training, Trust Fire Champion training). The focus of the *Business Continuity Plan* is taking appropriate action to maintain the safety of patients and staff, and a functional laboratory service. Risks considered include the following:

- Evacuation of a department due to fire, flooding, and/or contamination.
- Equipment or system failure including loss of power or other utilities, IT systems and/or communication systems.
- Planned or predicted service disruption i.e. industrial action, planned maintenance, etc.
- Severe staff shortages or unavailability of critical staff.
- Extreme weather conditions.

Action plans are periodically assessed, where possible (e.g. fire evacuation drills).

8 Management System Requirements

8.1 General Requirements

The laboratory uses Q-Pulse software to implement and maintain a Quality Management System that demonstrates the fulfilment of the clauses of BS EN ISO 15189:2022. Through the distribution and acknowledgement of this document, the departmental *QM Quality Policy* (GEN-QP-0001A) and *Pathology Annual Management Review* (GEN-QP-AMR Review); the laboratory ensures that its personnel are aware of departmental quality objectives and policies, their role in contributing to the effectiveness of the quality management system, and of the consequences of failing to conform with management system requirements (see also Section 6.2).

8.2 Management System Documentation

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 15189:2022. 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, staff competence and the consistent purpose of this organisation.

Laboratory Management is committed to the development, implementation, and continual improvement of its quality management system (QMS). This 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.
- 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: Organisational charts* – GEN-QP-0001D).

- Establishment of effective communication processes with staff and 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.

This Quality Manual outlines the structure of the Quality Systems in operation in the Pathology Department, identifying the arrangements for ensuring that the quality policy is adhered to by all staff. It describes the Quality Management Systems for the benefit of laboratory personnel, and provides information for users and regulatory/accreditation bodies.

The sections of the Quality Manual are arranged so that they equate with the clauses of the BS EN ISO 15189:2022 Standard. For each of the clauses, a brief description of the way in which the Pathology Department seeks to comply with the particular standard is provided, and references are given to appropriate procedures.

This Quality Manual 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 NWAFT Pathology Services website.

Q-Pulse access is available to all laboratory staff. Training and competence are documented in the People module of Q-Pulse. Q-Pulse access levels and privileges ensure that personnel are restricted to the parts of the QMS applicable to their staff grade.

8.3 Control of Management System Documents

SOP GEN-QP-DocCtrl: *Preparation and control of documents* describes the laboratory protocol for document control. The master list of all controlled documents is held on Q-Pulse. The PQM is responsible for all aspects of the document control system.

Relevant competent staff prepare new documents for approval. Each is uniquely identified by document and revision number within Q-Pulse. Before they are issued, these draft documents must be reviewed and approved by a senior member of laboratory staff or member of departmental clinical staff, using the Q-Pulse Approval function.

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. 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 to comply with Trust requirements.

Electronic copies of all Q-Pulse documents are stored on the Trust server and are backed up by the Trust IT Department. Electronic copies of documents are accessible via Q-Pulse software from any laboratory computer terminal. The issue of controlled hard copies in laboratory areas is performed only as per the 'Distribution of copies' component of each SOP. Changes to, and revision status of, existing documents are described in the 'Change details' section of the relevant Q-Pulse Document Record. These are also summarised on the 'Changes from previous revision' panel on the cover page of each SOP.

Q-Pulse access levels and privileges ensure that documents are protected from unauthorised access, unauthorised changes, or deletion. Documents accessed via Q-Pulse are presented to users in a read-only format. When a new document revision is created, the previous revision is stored indefinitely within the obsolete register of Q-Pulse. Obsolete documents are clearly identifiable as such. Hard copies of obsolete documents must be removed from laboratory areas upon issue of a new document revision.

8.4 Control of Records

The departmental 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) in conjunction with the Institute of Biomedical Science (IBMS). This document is stored in Q-Pulse as GEN-EXT-001. Storage facilities for laboratory records provide a suitable environment, such that access is restricted and loss due to damage or deterioration is minimised.

The laboratory protocols for the identification, storage, changes, archive, retrieval, retention time and disposal of laboratory records are described in SOP GEN-QP-QARecs (*Control of process and quality records*). Retention times as defined in this SOP are determined based on either legal liability or identified risks.
Where stored records are amended, both the original and amended data files are retained. Information relating to the date (and time) of alteration, an indication of the altered aspects, and personnel responsible for the alterations must also be logged.

8.5 Actions to Address Risks & Opportunities for Improvement

Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results. The identification of risks and opportunities for improvement will:

- Prevent or reduce the impact of nonconformities in laboratory activities.
- Achieve improvement, by acting on opportunities.
- Provide assurance that the management system fulfilling its purpose.
- Mitigate risks to patient care.
- Contribute to achieving the laboratory's quality objectives.

The laboratory management team is responsible for deciding which risks and opportunities need to be addressed. Any identified risks to patient care or service provision are logged on the Trust Risk Register using the Datix software (see SOP GEN-QP-Riskregister – *Pathology Risk Management and Register*). Any action taken to address these risks must be appropriate and proportional to their potential impact on patient safety or service provision (see also Section 7.1).

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 by raising a 'Staff quality improvement suggestion' or document 'Change request' via Q-Pulse. Staff improvement suggestions made during one-to-one discussions or departmental meetings must be formally logged as 'Staff quality improvement suggestions' on Q-Pulse by senior laboratory staff.

Opportunities for improvement might be identified and documented through a number of methods, including (but not restricted to):

- Staff improvement suggestions (submitted via Q-Pulse or departmental staff meetings/suggestions boxes, or Q-Pulse document change requests).
- User feedback (e.g. annual user satisfaction survey, complaints received via the Trust Complaints Department, suggestions raised in multi-disciplinary team [MDT] meetings).
- Patient feedback (e.g. complaints received via the Trust Complaints Department).
- Corrective and preventive actions in response to laboratory nonconformities (including those identified through internal quality control programmes and audit).
- Management review (e.g. through MGC meetings or the Annual Management Review).
- Feedback and results from external quality assurance providers.
- Feedback and reports from external auditors/assessors (e.g. UKAS, MHRA, HTA).
- Changes in external guidelines or standards (e.g. amendments to recommended examination methods in the investigation standards published by the Royal College of Pathologists [RCPath]).

8.6 Improvement

The laboratory is committed to continual service improvement, as specified in the Quality Policy (see also Section 5.5). Common means of identifying opportunities for improvement are outlined above. By committing to continual improvement, the laboratory promotes experiential learning amongst staff.

Actions taken to improve the quality of service are periodically reviewed for effectiveness. Such reviews might be performed through the 'Follow Up' component of the Q-Pulse CA/PA module, or through management review. These reviews

should include monitoring the levels of non-conformances traceable to the area or activity the quality improvement action is associated with.

The Laboratory produces 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. Laboratory quality objectives are defined annually and communicated to staff via the Annual Management Review (GEN-QP-AMR Review).

Progress towards achieving quality objectives and quality improvement is reviewed in MGC meetings, with feedback communicated to staff via departmental staff meetings.

8.7 Nonconformities & Corrective Actions

Procedures documenting the identification and control of nonconformities are described in SOPs Gen-QP-EvalQA (*Evaluation & Quality Assurance*) and GEN-QP-QIMPROVEMENT (*Quality improvement*).

When a nonconformity occurs, it should be recorded using the Trust Datix adverse event reporting system and/or the CA/PA module of Q-Pulse. For each identified nonconformity, the laboratory must take the following steps (see also Section 7.5):

1. Take immediate remedial actions to correct and control the nonconformity (recorded using the 'Remedial Action' function in the Q-Pulse CA/PA module). This might include the suspension of examinations and withholding of reports.

2. Investigate the nature of the nonconformity, and its potential consequences. This investigation **must** include an assessment of the likelihood of recurrence and whether similar nonconformities could potentially occur, and an assessment of the impact of the nonconformity upon the patient (recorded using the 'Investigate' function in the Q-Pulse CA/PA module). Where risks to patient care or service provision are identified through the investigative process, these should be logged on the Trust Risk Register using the Datix software (see also Section 8.5).

3. Determine the root cause of the nonconformity (recorded using the 'Root Cause' function in the Q-Pulse CA/PA module).

4. Evaluate the need for corrective or preventive actions to eliminate the identified root cause(s) of the nonconformity (recorded using the 'Corrective Action' function in the Q-Pulse CA/PA module). Proposed corrective and preventive actions must mitigate the identified cause(s) of the nonconformity and be proportional and appropriate to the magnitude of the risk to the patient. Identified actions might include changes to the laboratory's quality management system, if necessary.

5. Implement any necessary corrective actions, and preventive actions to address any similar nonconformities that could potentially occur.

6. Review and evaluate the effectiveness of the corrective/preventive actions (recorded using the 'Follow Up' function in the Q-Pulse CA/PA module). Where it is deemed necessary, the departmental Quality Officer may instigate a quality audit of the area or activity affected by the nonconformity. This audit will form part of the evaluation of the effectiveness of the corrective/preventive actions. The audit outcomes should be reported to the Quality Forum and/or Annual Management Review.

8.8 Evaluations

The Laboratory uses internal audit to provide evidence that the QMS is conformed to, effective, implemented and maintained across all departments. Details of the laboratory audit programme can be found in the laboratory *Quality Audit Manual* (GEN-QP-AudMan).

The laboratory has determined a number of quality key performance indicators (KPIs) which are used to evaluate performance in pre-examination, examination, and post-examination processes. These include target turnaround times for examinations, which have been agreed in discussion with service users.

The KPIs currently in use are detailed in the SOP GEN-QP-QImprovement (*Quality Improvement*).

KPIs are reviewed in MGC meetings and as part of the annual management review. They are updated periodically. User feedback is considered when updating Pathology KPIs. Evaluation of laboratory performance against these KPIs is used to assist in the determination of laboratory quality objectives.

A programme of horizontal, vertical and examination audits is agreed annually between the designated Quality Officers within each pathology discipline and the Pathology Quality Lead.

The purpose of the laboratory audit programme is to ensure that departmental pre-examination, examination, and post-examination processes meet the requirements of the patient and service user; and to assess departmental compliance with each of the BS EN ISO 15189 sub-clauses. Audit worksheet template documents have been devised and are available via Q-Pulse.

When agreeing the annual internal audit programme, activities are prioritised based on risk to the patient. The outcomes of previous evaluations (both internal and external), frequency of nonconformities, incidents, complaints and recent changes to laboratory processes are also considered. Each audit shall have specified criteria, objectives and scope.

Staff who perform audits are required to familiarise themselves with the Laboratory's quality system and have received Pathology audit training (logged via the *People* module of Q-Pulse). All staff within pathology are encouraged to undertake audit training and participate in audit activity. Wherever possible, the selected audit officer(s) will be independent of the laboratory area being audited, to provide objectivity and impartiality.

The owners of each audit are selected to ensure that the audit outcomes are reported to appropriate personnel. This typically means that the owner of each audit will be either the designated departmental Quality Officer, departmental Operational Manager, or Pathology Quality Lead. Audit outcomes are reported to the Quality Forum and/or Annual Management Review.

The laboratory/Trust is audited by the following external organisations:

- Care Quality Commission (CQC)
- Health & Safety Executive (HSE)
- 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 (Q-Pulse document GEN-QP-0001C).

Nonconformities identified through audit (both internal and external) are recorded using the CA/PA module of Q-Pulse. Remedial action, investigation, root cause analysis, and identification and implementation of any necessary corrective or preventive actions is conducted as per Section 8.7. Records of all completed audits are retained in the ‘Audit’ module of Q-Pulse.

8.9 Management Reviews

The MGC formally reviews performance of the QMS on an annual basis as part of its Annual Management Review (GEN-QP-AMR Review). This review is intended to ensure the continued suitability and effectiveness of laboratory activities, and define the laboratory’s stated objectives and policies (see also Section 5.5).

The AMR should evaluate inputs from various sources, including (but not restricted to):

- Status of actions agreed in the previous year’s AMR. Internal and external changes to the management system.
- Fulfilment of quality objectives.
- Effectiveness of any actions taken to address identified risks and opportunities for improvement.
- Changes to, and recommendations for improvement of, the QMS.
- Changes in the quantity and type of laboratory activities.
- Suitability of policies and procedures, including a review of user requests and sample requirements.

- Adequacy of resources (see also resource requirements defined in Section 6).
- Outcomes of recent evaluations, including those performed by external organisations.
- Laboratory performance in terms of delivering patient care, measured through KPIs.
- Patient, user, and staff feedback/complaints.
- Quality assurance of result validity (to include discussion of both IQC and EQA data).
- Performance of external providers and suppliers.
- Evaluation of POCT activities.
- Nonconformities, including patterns or trends that might indicate inadequacies in laboratory activities.
- Departmental training and education programmes.

The findings of the AMR are formally documented and forwarded to the Pathology MGC for formal ratification subsequent to publication within the Documents Module of Q-Pulse. The finalised AMR document (GEN-QP-AMR Review) is published and distributed electronically to all staff. It represents a record of decisions and actions relating to at least the following:

- The effectiveness of the QMS.
  Laboratory activities in terms of meeting the needs of patients and users.
- Laboratory activities in terms of meeting the requirements of BS EN ISO 15189.
- The provision of required resources.
- Any requirement for change.

9 References

Pathology Department documents, accessible via Q-Pulse:

- GEN-MF-SLA-Winpath: *SLA-CliniSys*
- GEN-MP-PatConf: *Patient Confidentiality*
- GEN-QP-DataMgt: *Management of Data & Information*
- GEN-QP-LabDirector: *Laboratory Director*
- GEN-TOR-H&SCommittee: *Terms of Reference – Pathology H&S Committee*
- GEN-QF-H&SAgenda: *Pathology Health and Safety Agenda*
- GEN-TOR-ITFORUM: *Terms of reference – IT forum*
- GEN-IT-Agenda: *IT Forum Agenda*
- GEN-TOR-QualityForum: *Terms of Reference – Pathology Quality Forum*
- GEN-QF-QualityforumTemp: *Pathology Quality Forum Template*
- GEN-TOR-ELD: *Terms of Reference – Education & Training Group Forum*
- GEN-QF-TrainingAgenda: *Pathology Training forum agenda*
- GEN-QF-DeptMeetingTemp: *Pathology Departmental Meeting Template*
- GEN-EXT-FISSGOVSTRUC: *FISS Governance Structure*

- GEN-QP-QPulseManage: *Q-Pulse User Account Management & Access Privilege Levels*
- GEN-QP-CHANGECTRL: *Change Control Overview SOP*
- GEN-QP-PersonnelMgt: *Personnel Management*
- GEN-TRN-001a: *Local Induction Checklist*
- GEN-TRN-POLICY: *Pathology Training Policy*
- GEN-TRN-Pathology training records on Q-Pulse: *Pathology training records on Q-Pulse*
- GEN-EXT-001: *Guidelines for the Retention and Storage of Pathological Records, Archives and Specimens*
- GEN-QP-QARECS: *Control of process and quality records*.
- GEN-MP-EqpProc: *Procurement of Pathology Equipment*
- NWA GEN-QP-Validation&Verification in Pathology: *Validation & Verification in Pathology*
- GEN-MP-SuppliesProcure: *Procurement of services and supplies*
- GEN-MP-SLA: *Service Agreement (SLA) Procedure*
- GEN-QP-Referral: *Referral to other laboratories*
- GEN-QP-Riskregister: *Pathology Risk Management and Register*
- GEN-QP-ClnMtrl: *Control of clinical material*
- GEN-QP-EvalQA: *Evaluation & Quality Assurance*
- GEN-QP-QImprovement: *Quality Improvement*
- GEN-QP-QPULSECAPA: *Q-Pulse CAPA*
- GEN-QP-DATIX: *Trust adverse event reporting via Datix*
- GEN-MP-BsCnPln: *Pathology Business Continuity Plan*
- GEN-QP-Complaints: *Complaints and Feedback*
- GEN-QP-AMR Review: *Pathology Annual Management Review*
- GEN-QP-DocCtrl: *Preparation and control of documents*
- GEN-QP-AudMan: *Quality Audit Manual*

NWAFT policies, accessible via the Trust intranet:

- *Conflicts of Interest Policy*
- *Gifts, Hospitality and Sponsorship Policy*
- *Freedom to Speak Up: Raising Concerns in a Safe Environment*
- *Duty of Candour Policy*
- *Professional Clinical Registration Policy*
- *Induction Policy*
- *Appraisal & Development Policy*
- *Contracting Policy*
- *Complaints Policy Procedure for dealing with patient and service user complaints*
- *Resolution Policy*

NWAFT mandatory training programmes, accessible via the NHS Electronic Staff Record (ESR):

- *Information Governance and Data Security*
- *Patient Safety – Level 1*

- *Safeguarding Adults*
- *Safeguarding Children*
- *Equality, Diversity & Human Rights*
- *Fire Safety*

External publications:

- *BS EN ISO 15189:2022: Medical laboratories – Requirements for quality and competence,* published by the International Organisation for Standardisation (ISO)
- *ISO/IEC 17043:2023: Conformity assessment – General requirements for the competence of proficiency testing providers*, published by the International Organisation for Standardisation (ISO)
- *BS EN ISO 17025:2017: General requirements for the competence of testing and calibration laboratories,* published by the International Organisation for Standardisation (ISO)
- *BS EN ISO 17034:2016: General requirements for the competence of reference material producers,* published by the International Organisation for Standardisation (ISO)
- *UN3373: Packaging and transport requirements for patient samples* and *Packing Instruction P650*, as published by the Department for Transport (DfT)
- *NWAFT Pathology Services* website
- *TPS 47: UKAS policy on participation in proficiency testing,* published by the United Kingdom Accreditation Service (UKAS)
- *Guidelines for the Requirements for the Competence of Providers of Proficiency testing Schemes*, published by the International Laboratory Accreditation Cooperation (ILAC)

10 Appendices

All appendices for the Quality Manual are available as separate documents via Q-Pulse:

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