**Quality Manual**

**Scarborough, Hull, York Pathology Service**

**York & Scarborough Hospitals**

***(Formally known as Laboratory Medicine)***

‘Right Patient, Right Test, Right Result, Right Time, Right Support’

**Changes from last version of this document**

General updates including

CR6847: Trust S&N now DIS

CR6934: LM-INF-UKAS LAB1 has been replaced by LM-INF-GEN 6

CR6935: Reference to the name Laboratory Medicine amended throughout the document. Laboratory Manager renamed Head Biomedical Scientist in the organisational charts.

CR6936: Section 4.1.1.2 removal of the organisation Monitor, added a link to the compliance certificate.

CR7481: Added BT-SOP-CONT PLAN to section 5.10.3

CR7613: Page 10 POCT services also provided on BH site

CR7614: Added reference to PC-INF INDUCTION & PC-INF-TRAINMAN 5.1.4

CR7616: Section 5.6.3.1 added reference PC-SOP-EQA

CR7617: Section 5.6.4: added reference to PC-SOP-ADV

CR7618: Added PC-SOP-CONT PLAN to section 5.10.3

Page. 24: LM-POL-REFERRAL has been replaced by SHY-POL-REFERRAL

Page. 58: Transfusion Quality Assurance Policy (BT-POL-QA) has now been included in section 5.6.2

Page 68: Update for new Care Group Structure

Page 69: Update of Clinical Leadership organisational chart

Page. 71: Update to the SHYPS senior management organisation chart

Page. 76: Creation of the blood science specimen reception organisation chart

Page. 78: Addition of the Network Chief BMS to the Microbiology organisation chart

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**Quality Manual and the Use of the UKAS Logo**

This document, together with the processes and procedures specified within represents the Quality Management System of the Scarborough, Hull York Pathology Service (SHYPS) on the York & Scarborough Hospital Sites. It has been compiled to meet the requirements of ISO 15189; the internationally recognised standard used by the United Kingdom Accreditation Service (UKAS) in confirming the competence of medical laboratories.

1. **Use of UKAS logo:**

In accordance with UKAS guidelines and compliance requirements, all UKAS accredited organisations, such as our UKAS accredited laboratory departments, wishing to use the national accreditation symbols must do so in accordance with the conditions detailed in Accreditation Logo

* Symbols - The National Accreditation Logo and Symbols: Conditions for Use by UKAS and UKAS Accredited Organisations.

Please see links below for further details and compliance:

LM-POL-ACCREDLOGO: National accreditation logo and symbols: conditions for use

<https://www.gov.uk/government/publications/national-accreditation-logo-and-symbols-conditions-for-use>

Consideration throughout this document is given to appropriate national and international standards. In particular, the requirements for compliance with the Human Tissue Act 2004 (HTA), Blood Safety and Quality Regulations 2005 (MHRA), the Guidelines for national screening programme (Screening quality assurance service SQAS) and the Health and Social Care Act (CQC).

**Consideration of accreditation Status:**

The UKAS document ‘Reference to accreditation and multilateral recognition signatory status by UKAS accredited bodies’ [LM-INF-GEN 6], states that ‘Reference to UKAS accreditation shall be displayed on all test reports that contain results from tests that are within the accredited scope of the laboratory and that it has itself carried out’, and that reference should be made by incorporation of the accreditation symbol or use of the wording ‘UKAS accredited’. It also states that ‘When reports or certificates incorporating reference to UKAS accreditation contain results from both accredited and non-accredited tests and/or sampling, the non-accredited work shall be clearly identified as Not UKAS accredited’.

As a laboratory SHYPS have reviewed Gen 6 and considered the risk of having overly complex reports, which may confuse the service users and have made the decision to only note which elements are not accredited.

**UKAS and other accreditation/regulatory normative documents:**

The term "normative document" is a generic term that covers such documents as standards, technical specifications, codes of practice and regulations.

In accordance with ISO 15189:2012 standard requirements, all normative documents, such as UKAS technical policy statements and accreditation or regulatory guidelines should be referenced in applicable standard operating procedures (SOPs) as defined in document control process. These documents should be cross-checked in the source website to ensure it is the most updated standards or guidelines.

The UKAS document General Principles for the Assessment of Conformity [LM-INF-GEN 1] provides guidance on the application of ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories to multi-site laboratories and describes how UKAS assesses and refers to multi-site laboratory accreditations. The laboratories on the York & Scarborough hospital sites have written a policy statement to show how they ensure they comply with this document and are considered as a multi-site laboratory [LM-POL-MULTI SITE].

All processes and procedures specified herein are mandatory within the Pathology Service on the York & Scarborough Hospital sites.

Information regarding the distribution and review history of this document can be found in the Q-Pulse document control system.

SHYPS Network Quality Manager

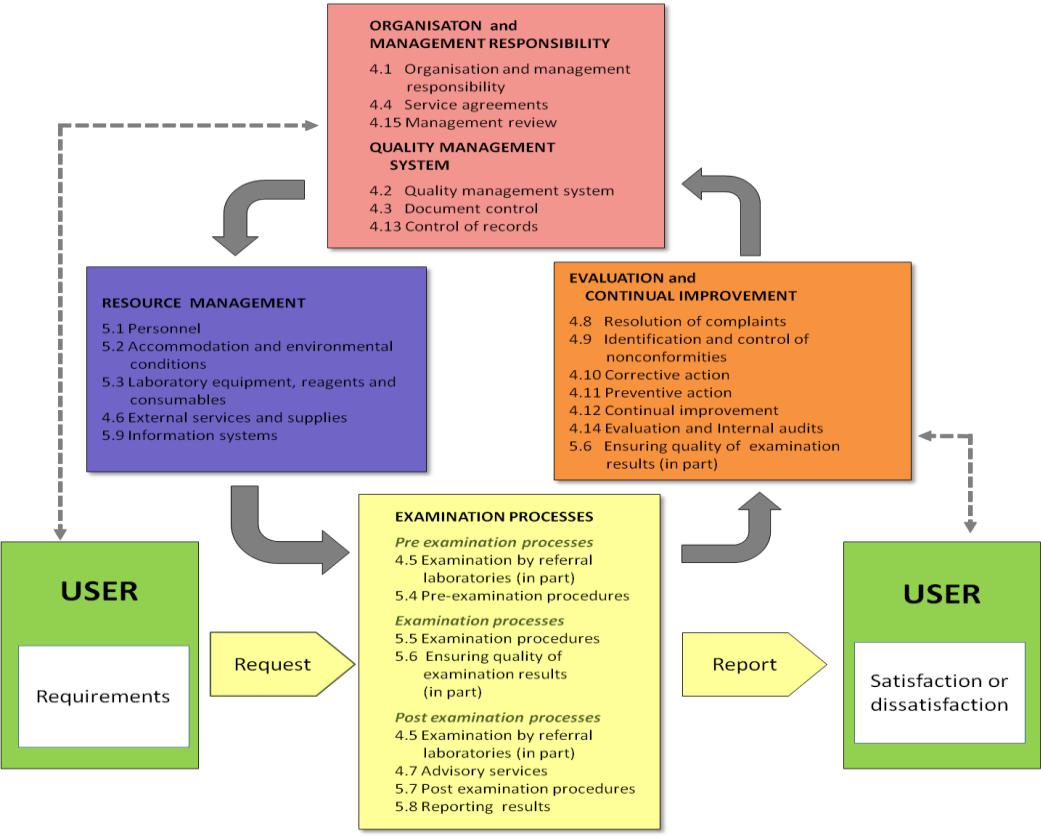
# General Information

## 1.1 Purpose

This Quality Manual describes the Quality Management System (QMS) in use throughout the York & Scarborough laboratories for the benefit of management, staff, service users and accreditation and regulatory bodies. The QMS is the process developed to support the generation of an efficient, 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.

This Quality Manual demonstrates each specific discipline’s ability to execute the indicated repertoire and to meet regulatory requirements. The sections of the Quality Manual are arranged so that they equate with the format of the management and technical requirements of ISO 15189. Under the title of ISO 15189 sub clause there is a brief description of the way in which SHYPS York & Scarborough laboratories, as part of York and Scarborough Teaching Hospitals NHS Foundation Trust (YSTHFT), seeks to comply with the sub-clause and references are given to appropriate Trust policies and procedures, and key departmental supporting policies and procedures. Throughout the text there are references to documentation, indicated by square brackets, or presented in tabular format and hyperlinks to facilitate movement to relevant sections within the document itself and external documentation within the Trust for the electronic reader.

The sections of the standards should be seen to relate to each other as shown in Figure 1:



**Figure 1: The main sub-clauses of ISO 15189 reordered into a process based model of a QMS**

## 1.2 Scarborough, Hull, York Pathology Service (SHYPS)

SHYPS is a clinically led pathology network that incorporates a range of laboratory disciplines across 4 acute hospital sites: Hull Royal Infirmary (HRI), Castle Hill Hospital (CHH), York Hospital (YH) and Scarborough Hospital (SH). SHYPS also covers numerous communities, specialist, and primary care facilities across a wide geography. SHYPS provides over 26 million tests per annum, several specialised pathology services are also provided including neuropathology, virology, and immunology. Approximately 50% of the laboratory workload is generated from GPs or other out of hospital services (model hospital data set). SHYPS combines the pathology services of York and Scarborough Teaching Hospitals NHS Foundation Trust (YSTHFT) and Hull University Teaching Hospitals Trust (HUTH). SHYPS is a collaborative joint venture. The partner organisations of the collaborative joint venture are YSTHFT and HUTH.



**York & Scarborough Teaching Hospitals NHS Foundation Trust (YSTHFT)** provides a comprehensive range of acute hospital services. York Teaching Hospital NHS Foundation Trust was granted foundation status on 1 April 2007. In April 2011 the Trust took over the management of community-based services in Selby, York, Scarborough, Whitby and Ryedale and in July 2012 acquired Scarborough and Northeast Yorkshire Healthcare NHS Trust, bringing Scarborough and Bridlington Hospitals into the organisation. In April 2021 the Trust updated its name to York & Scarborough Teaching Hospitals NHS Foundation Trust. It serves approximately 800,000 people living in and around York, North Yorkshire, Northeast Yorkshire and Ryedale – a mixed urban and rural population across 3,400 square miles.

**Hull University Teaching Hospital NHS Trust (HUTH)** has a comprehensive clinical portfolio, covering the major medical and surgical specialties, routine and specialist diagnostic services and other clinical support services. It serves approximately 600,000 people in the Hull and East Riding of Yorkshire and operates from two main sites - Hull Royal Infirmary and Castle Hill Hospital – whilst delivering several outpatient services from locations across the local health economy area. HUTH provides specialist and tertiary services to a catchment population of between 1.05 million and 1.25 million extending from Scarborough in North Yorkshire to Grimsby and Scunthorpe in Northeast and North Lincolnshire respectively.

The vision for the network is to provide an efficient and sustainable pathology service that meets the needs our local community. SHYPS is patient-focused and recognizes the absolute requirement to provide a high-quality analytical service supplemented by sound clinical advice. To us every sample is a precious sample. Our pathology service is exactly that — a service. We are committed to not only delivering a high-quality service but making the network a rewarding place to work. Our mission statement is:

*‘To provide an excellent, high quality, patient focused pathology service, which is sustainable, innovate and research led. Creating improved opportunities and development for our team(s)’*

SHYPS aims to deliver a service across 4 acute hospital sites that share a unified management structure [(Appendix 1 – Organisation Chart 5 SHYPS Senior Management Structure)](#_Organisation_Chart_(5):) with a single Quality Management System; however; at present there are two separate QMS which will be unified as the Network evolves. It must be emphasised that this Quality Manual applies solely to the York & Scarborough Hospital sites. As far as possible, policies and procedures will apply to both the York & Scarborough sites. **Many of the policies and procedures still refer to the historic name of Laboratory Medicine and will be updated in due course.** At a discipline specific level, it is envisaged that there will be identical analysers and processes across the two sites providing compatibility of results. Provision of service, for example out-of-hours, will also be harmonised and this will be delivered through a shift system and extended working day on both sites. The expectation is that users of the service should see no significant difference in the level of service provided on either site irrespective as to whether samples are sent to York or Scarborough for processing.

**The postal address for the Scarborough Laboratory is:**

Pathology

Scarborough Hospital

Woodlands Drive,

Scarborough, YO12 6QL

**The postal address for the Hull Laboratory is:**

Pathology

Hull Royal Infirmary

Anlaby Road,

Hull, HU3 2JZ

**The postal address for the York Laboratory is:**

Pathology

York Hospital

Wigginton Road

York, YO31 8HE

## 

## 1.2 Laboratory Service Scope

**1.2.1 Blood Sciences**

**Haematology and Blood Transfusion:**

The Haematology and Blood Transfusion service is provided on all sites; HRI, CHH, YH and SH.

Haematology, including Blood Transfusion provides a high-quality diagnostic service and is committed to achieving and maintaining the highest possible standards, delivering a 24 hour/365 day comprehensive consultative and diagnostic service. Haematology participates in the antenatal and newborn screening program, designed to detect those pregnancies where there is the risk to the foetus of having a clinically significant haematological disorder. In addition, the Haematology laboratory at HRI supports the Haemophilia centre.

The Blood Transfusion department provides blood products for use in clinical emergencies and routine procedures.

**Clinical Biochemistry:**

The Clinical Biochemistry service is provided on all sites; HRI, CHH, YH and SH.

Clinical Biochemistry provides a 24 hour/365-day high quality consultative and analytical service to assist in the rapid diagnosis of disease. A full range of biochemical analysis on serum and urine samples is provided; including routine biochemistry, endocrinology, toxicology and specific protein analysis, sweat tests for cystic fibrosis and glucose tolerance tests.

**Immunology:**

The Immunology service is provided mainly from the HRI site. A full range of immunology testing is provided on blood and serum specimens, including clinical immunology and allergy, autoimmunity, immunochemistry and flow cytometry.

**Point of Care Testing (POCT):**

POCT provides a comprehensive service on all sites; HRI, CHH, YH, SH and BH.

The POCT team provides training and support for users on the main Hospital sites and also satellite units such as Easingwold and the community. The team covers all POCT, ranging from dipsticks to sophisticated analytical instruments.

**1.2.2 Cellular Pathology and Microbiology/Virology**

**Microbiology and Virology:**

The Microbiology service is provided from the HRI, and YH sites, predominantly Virology is based on the HRI site.

Microbiology offers a high quality, 24-hour interpretative diagnostic Microbiology service. As well as routine bacteriological culture, the department offers serological testing, liquid mycobacterial culture and rapid molecular detection techniques for the diagnosis of chlamydia. Microbiology works in collaboration the UK Health Security Agency and Office for Health Improvement and Disparities (formerly Public Health England) to contribute to epidemiological surveillance and public health medicine.

Microbiology participates in the antenatal and newborn screening programme, designed to detect those pregnancies where there is the risk to the foetus from a set criterion of infectious diseases, notably HIV, hepatitis B and syphilis.

**Cellular Pathology:**

Histopathology and Cytopathology are provided on the HRI and YH sites. Neuropathology is provided on the HRI site. An Andrology service is also available on the YH site.

A full range of histological tests are available including routine histological techniques and a wide range of special staining methods. Rapid diagnosis is available through the utilisation of frozen section techniques. Immunohistochemistry provides a comprehensive repertoire of antibodies to identify tissue antigen sites as an aid to diagnosis, particularly in cancer and specific molecular markers are also available. Cytopathology provides a high-quality diagnostic service for non-gynaecological cytology. The laboratory at HRI provides a neuropathology service linked to a wider regional neuropathology reporting team (Sheffield and Leeds). Electron microscopy is provided by the unit at Central Manchester and Manchester Children’s Hospital Trust.

The team of Histopathology Consultants specialise in the complete range of body tissues and organs and support Multi-Disciplinary Team Meetings for all specialities, except paediatrics. There are specialist leads (and deputies) in:

Breast Cardiothoracic

Upper GI Urology

Lower GI Gynaecology

Renal pathology Dermatology

Head and Neck Paediatrics

**1.2.3 Central Service**

The SHYPS central service supports the pathology functions common to all discipline specific services: Quality Management, Training, IT, Innovation, Finance and Business Management.

## 1.3 Quality Policy

The SHYPS Quality Policy [SHY-POL-QUALITY] encompasses the values, drivers, and motivations of the Trust mission statement as well as the specialities own quality objectives. The Quality Policy is displayed throughout the laboratory environment for staff and to our users through the YSTHFT Website which can be found as stated below in section 1.4 Information on York & Scarborough Hospitals Pathology Services.

## 1.4 Information on SHYPS Services

A guide to the Pathology Service is available to all users through the official YSTHFT website, A-Z of Services which includes Pathology/Laboratory Medicine:

[**York & Scarborough Hospitals Website**](https://www.yorkhospitals.nhs.uk/our-services/a-z-of-services/laboratory-medicine1/)

The information contained on the website is reviewed annually, (although it may be revised more frequently if significant changes occur in any department). At times of review, heads of department are advised that review is underway and are expected to review information pertaining to their own departments. Required changes are made through the Q-Pulse Document Module [(see 4.3](#page24) [Document Control).](#page24) Pathology does not produce a hardcopy handbook owing to difficulties in control, cost and updating.

More information about Hull University Teaching Hospitals NHS Trust is available on the Trust website. A Pathology Intranet site is available for our service users within the Trust called ‘Pattie’.

[Hull University Teaching Hospitals NHS Trust (hey.nhs.uk)](https://www.hey.nhs.uk/)

# References

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

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

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

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

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

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

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

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 – the ‘Orange Guide’

Trust Management Policies and Procedures – available via [Staff Room](http://staffroom.ydh.yha.com/) Trust intranet site. URL links to Trust documentation have been included in Q-Pulse to maintain corporate document control integrity.

# Definitions & Abbreviations

For the purposes of this Quality Manual, the terms and definitions given in ISO 15189 apply.

|  |
| --- |
| Accreditation – Procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks. |
| Alert interval/critical interval – Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death. |
| AMR – Annual Management Review. |
| Audit – systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (Clinical audit is audit applied to clinical activities) |
| Automated Selection and Reporting of Results – Process by which patient examination results are sent to the Laboratory information system and compared with laboratory defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention. |
| BMS – Biomedical Scientist |
| CHH- Castle Hill Hospital |
| CPD – Core Patient Database. The Trust clinical area for requesting and viewing patient records. |
| CQC – Care Quality Commission |
| Corrective Action – Action to eliminate the root-causes of a detected non-conformity / non-compliance or other undesirable situation. |
| Critical Test Result - Defined as a result indicating an immediate risk to the patient of injury or death. |
| CSCS- Cancer, Specialist and Clinical Support Services (CSCS) |
| DATIX - The Trust web-based incident reporting and management system. |
| Documented procedure – Specified way to carry out an activity or a process that is documented, implemented and maintained. Standard Operating Procedure (SOP). |
| HUTH – Hull University Teaching Hospital NHS Trust |
| HRI – Hull Royal Infirmary |
| BH – Bridlington Hospital |
| ICE - Integrated Clinical Environment. A software system that allows clinicians to make electronic pathology requests and receive results electronically. |
| ISO – Medical laboratories – Requirements for quality and competence (ISO 15189:2012) Nonconformity – Nonfulfillment of a requirement. |
| POCT – Point of Care Testing: testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient. |
| Policies – Policies “provide a statement of intent’ that an organisation will follow a particular course of action. |
| Post-Examination Processes (Post-Analytical Phase) - Processes that follow the examination, include: review of results, retention and storage of clinical material, sample (and waste) disposal, formatting, releasing, reporting and retention of examination results. |
| Pre-Examination Processes (Pre-Analytical Phase) - Processes that start, in chronological order, from the clinician’s request and include: the examination request, preparation and identification of the patient, collection of the primary sample(s), transportation to and within the laboratory, and end when the analytical examination begins. |
| Preventive action – a pro-active process to identify opportunities for improvement or to avoid a potential non-conformity / non-compliance. |
| Primary Sample (Specimen) - Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole. |
| Procedures - Procedures 'provide the information to carry out the intent' defined by a policy Quality - The degree to which a set of inherent characteristics fulfils requirements. |
| Quality Indicator - Measure of the degree to which a set of inherent characteristics fulfils requirements. |
| Quality Management System - A management system to direct and control an organisation with regard to quality (QMS). |
| Quality Objective – something sought, or aimed for, related to quality. |
| Record - Any information that produces evidence (e.g., requests, examination results and reports, instrument printouts, laboratory workbooks and worksheets, accession records, calibration records, quality control records, audit records, complaints and action taken, external quality assessment records, instrument maintenance records, incident / accident reports, staff training and competency records, personnel records). |
| Referral laboratory – external laboratory to which a sample is submitted for examination. |
| Remedial action – action taken at the time of a non-conformity to mitigate its immediate effects. (It should be followed by corrective action to remove the root cause of the problem – see above). |
| SHYPS – Scarborough, Hull, York Pathology Service |
| SH – Scarborough Hospital |
| Trust – York & Scarborough Teaching Hospitals NHS Foundation Trust (YSTHFT). |
| User – person or organisation using the services of the laboratory. |
| User Satisfaction – user opinion of degree to which the service provided has met their requirements. |
| Validation – Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. |
| Verification – Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. |
| Working instructions – These are practical day to day instructions. Instructions should normally be embedded in a procedure document, and if published separately should refer back to the procedure. |
| YH – York Hospital |
| YSTHFT – York & Scarborough Teaching Hospitals NHS Foundation Trust |

# 4.0 Management Requirements

## 4.1 Organisation and Management Responsibility

### 4.1.1 Organisation

#### 4.1.1.1 General

The laboratory shall meet the requirements of ISO 15189:2012 when carrying out work at its’ permanent facilities or associated facilities (point of care) for which the laboratory has full or shared responsibility. The scope of the laboratory is detailed in the [General Information](#page8) section of the Quality Manual. This Quality Manual [LM-INF-QUALMAN] explains, standard clause by standard clause, how this is achieved.

#### 4.1.1.2 Legal Entity & Oversight

The partner organisations of the collaborative joint venture are York and Scarborough Teaching Hospitals NHS Foundation Trust (YSTHFT) and Hull University Teaching Hospitals Trust (HUTH). YSTHFT is the host Trust and legal entity. YSTHFT is also registered with the Care Quality Commission (CQC) (YT-INF-CQC REG). YSTHFT is the entity that is held legally responsible for all its activities and, under the terms of the Health and Social Care Act (2012) is assessed for regulatory compliance against the act by the CQC.

The NHS England compliance certificate can be found on the NHS England website following the link below.

[NHS England » York and Scarborough Teaching Hospitals NHS Foundation Trust](https://www.england.nhs.uk/publication/york-teaching-hospital-nhs-foundation-trust/)

The NHS Litigation Authority is the administrator of the Liabilities Third Parties Scheme (LTPS) covering NHS organisations in England and confirms membership of YSTHFT [LM-REC-INSURE].

The YSTHFT organisational chart can be found in [Appendix 1 – Organisation Chart 1](#_Organisation_Chart_(1):). SHYPS is part of Cancer, Specialist and Clinical Support Services (CSCS). An organisational chart for the Operational Management Structure of CSCS can be found in [Appendix 1 – Organisation Chart 2](#_Organisation_Chart_(2):). As defined in the SHYPS collaboration agreement; a single oversight committee ensures strategic oversight of the provision of the pathology service and open, transparent communication between the partner Trusts ([Appendix 1 – Organisation Chart](#page83) 3).

The Trust’s ultimate objective is ‘to be trusted to delivery safe, effective, and sustainable healthcare to our communities’. Its values, drivers and motivations are:

• Patients are at the center of everything we do

http://staffroom.ydh.yha.com/about-the-trust/files-to-link-to/Valuesstrip_FINAL.PNG/@@images/image/preview• Caring about what we do

• Respecting and valuing each other

• Listening in order to improve

• Always doing what we can to be helpful

#### 4.1.1.3 Ethical Conduct

SHYPS will deliver its service to clinicians and their patients in an ethically sound and transparent manner, ensuring that the specific requirements are met:

1. The laboratories will conduct its affairs in ways to ensure that it retains clinicians’ and patients’ confidence in its competence, impartiality, judgement, and operational integrity.
2. Management and personnel are free from undue internal and external commercial, financial or other pressures which may adversely affect the quality of their work.
3. If there are potential or real conflicts of interest, these are transparently and appropriately declared.
4. There are arrangements to ensure that human tissue samples or remains are treated according to relevant legal requirements.
5. Confidentiality of information is maintained.

To achieve these requirements, SHYPS will:

* Require and ensure that all medical, scientific and practitioner staff are members of the appropriate voluntary or statutory register and follow the appropriate professional codes of conduct.
  + Trust: Maintaining Professional Registration Guidance [YT-POL-PROF REG]
* Pathology will comply with specific arrangements established by the YSTHFT with regards to the following, which support fairness, equality, and high standards of business and professional practice. SHYPS will comply with the YSTHFT policy on maintaining a register of staff (and close relatives and associates) external business interests, ensuring when there is a conflict of interest, staff involved do not take part in any decision-making associated with that area, including authorities to purchase.
  + Trust: Standing Financial Instructions: [YT-POL-SFI]
  + Trust: Procurement Policy: [YT-POL-PROCURE]
  + Trust: Fraud, Bribery and Corruption Policy: [YT-POL-FRAUD]
* Ensure staff compliance with the Trust policy on acceptance of gifts from third parties:
  + Trust: Standards of Business Conduct Policy: [YT-POL-BUSINESS]
* Ensure management of staff absence according to Trust policy
  + Trust: Agenda for change Sickness & Absence Policy and Procedure: [YT-POL-SICKNESS]
  + Sickness Absence Policy (Medical & Dental staff): [YT-POL-SICKNESS MED]
* Ensure that staff are aware of the Trust Whistleblowing policy:
  + Trust: Raising Concerns and Whistle blowing Policy [YT-POL-CONCERN]
* Ensure there are appropriate policies and procedures for consent, collection, transportation and storage of human samples, tissues and remains. An example of which is:
  + Policy for Release of Samples: [LM-POL-RELEASE]
  + York & Scarborough Teaching Hospitals NHS Foundation Trust has been granted HTA licence (Licence number 12093) in the post-mortem sector confirming continuing acceptability for activities.
* Require and ensure all staff participates in the YSTHFT Statutory Mandatory Training Program. The ethical conduct expected from all staff is outlined at YSTHFT Corporate Induction. Information Governance training is included as part of the on-going training programme recorded on the Learning Hub entered via YSTHFT Intranet site Staff Room.
  + Trust: Information Governance Staff Guides: [YT-INF-INF GOV]
* Ensure controlled access to areas where confidential information may be viewed and ensure controlled access to IT systems where confidential information is stored and staff are aware of procedures:
  + Trust: Security Policy [YT-POL-SECURITY]
  + Trust: Data Protection Policy: [YT-POL-DATA PROT]
  + Laboratory Medicine Security Policy [LM-POL-SECURITY]

#### 4.1.1.4 Laboratory Director

ISO 15189:2012 requires that the laboratory be directed by a person or persons with the competence and delegated responsibility for the services provided. The Director’s responsibilities include professional, scientific, consultative, or advisory, organisational, and educational matters relevant to the services offered by the laboratory as defined by the standard. ISO 15189: 2012 states that the laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory. The standard also states that the duties and responsibilities shall be documented.

The SHYPS Pathology Group Director has ultimate accountability for the overall operation and direction of SHYPS. The SHYPS Pathology Group Director reports and is accountable to the CSCS Clinical Director who sits on the Trust executive board. The organisation charts presented in [Appendix 1](#page81) clearly defines the hierarchy within SHYPS and its’ position with the YSTHFT and Care Group as a whole.

Duties and responsibilities as specified within ISO 15189:2012 of the Laboratory Director are devolved to designees as appropriate. This is defined in the document: Pathology Group Director Role Specification and Delegated Responsibilities Summary [SHY-INF-PGD].

### 4.1.2. Management Responsibility

#### 4.1.2.1. Management Commitment

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

1. Ensuring that all laboratory personnel are aware of and comply with the needs and requirements of service users [(4.1.2.2)](#page19) as well as regulatory and accreditation requirements.
2. Establishment of the departmental Quality Policy [(4.1.2.3).](#page20)
3. Ensuring that quality objectives and plans to achieve these objectives are in place [(4.2.2.4).](#page20)
4. Defining responsibilities, authorities and interrelationships of all personnel [(4.1.2.5).](#page20)
5. Establishment of effective communication processes with staff and also with the service stakeholders [(4.1.2.6).](#page21)
6. Establishment of the role of Laboratory Network Quality Manager [(4.1.2.7).](#page22)
7. Ensuring that management reviews occur on at least an annual basis [(4.15).](#page37)
8. Ensuring that staff are competency assessed to provide assurance that they are competent to perform their assigned activities [(5.1.6)](#page41)
9. Ensuring that there are adequate resources (see [5.1,](#page38) [5.2](#page43) & [5.3](#page47)) to enable the proper conduct of pre-examination, examination and post-examination activities (see [5.4, 5.5](#page53) & [5.7)](#page67).

#### 4.1.2.2. Needs of Users

SHYPS reviews the service provided to ensure that it meets the needs of service users and the patient population it serves.

* The ward managers and hospital doctors are surveyed regarding the pathology service.
* The practice managers are surveyed regarding the pathology service.
* Service level agreements are arranged with other users, including other hospitals and private laboratories, on request.

Surveys which have been performed which are recorded in the Q-Pulse Document module under audit as in the examples below. The response rate for these surveys was poor, and alternative methods have been sought, by issuing ‘post cards’ and requesting feedback on the website. This has also proved difficult and in the future other methods may be explored:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Survey of Laboratory Users York & Scarborough** | **LM-AUD-ALL USER SURV** |

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

Complaints received from users are fully investigated and any necessary corrective actions undertaken. All adverse incidents concerning the Pathology are encouraged to be reported using the YSTHFT Risk Management Tool Datix according to the YSTHFT Incident Management Policy [YT-POL-AIRS] and are simultaneously recorded in the Q-Pulse CAPA module to effectively manage pursuant corrective actions.

Assessment of user feedback is performed by the Quality Manager and reported to the SHYPS Senior Management Team through the SHYPS Governance Meeting in a format which can be fed back to the individual disciplines to notify staff and be included in the SHYPS Annual Management Review.

#### 4.1.2.3. Quality Policy

The SHYPS Quality Policy featured in section 1.3, is published as a controlled document [SHY-POL-QUALITY] which is distributed to all staff and displayed within the laboratory. The Quality Policy meets the requirements of this International Standard and is appropriate to the purpose of this organization. It is reviewed annually to ensure continuing suitability as part of the management review process.

#### 4.1.2.4. Quality Objectives and Planning

The SHYPS Operational Plan outlines the strategy of SHYPS as it progresses to a mature Network monitored by the NHSE/I Network Maturity Index. The strategy has been developed to meet the challenges and needs of our community and local health economy, taking into consideration:

• the capacity and demand challenges highlighted in the recent review of pathology services

• the changes in technology and diagnostic requirements across England and particularly for our region

• the availability and development opportunities for new diagnostics, new patient pathways and breaking down of traditional boundaries for delivering diagnostic services.

Our strategy provides a framework and direction for pathology services that will ensure our region has an innovative and sustainable pathology service capable of adapting to the changing needs of clinicians and patients.

The SHYPS Board oversees the review and development of the plan which is presented to the Oversight Committee. SHYPS is accountable to NHSE/I for its progression as a Network.

Specific objectives which relate to the overall SHYPS strategy are defined within individual workstreams and are recorded within the annual management review. Management review is ongoing at both discipline specific and SHYPS Senior Management Team Meetings and determines whether the objectives have been successfully completed and provides an opportunity for revising objectives and plans and the functioning of the quality management system.

#### 4.1.2.5. Responsibility, authority and interrelationships

The line of responsibility for clinical performance runs from the Chief Executive of the YSTHFT through the Medical Director of the YSTHFT, the CSCS Medical Clinical Director and the SHYPS Pathology Group Director to the Lead Clinician for each discipline. The SHYPS Pathology Group Director is responsible to the YSTHFT Medical Director for the quality and scope of the service provided by SHYPS, its Consultant Pathologists and Clinical Scientists.

The Operational Management responsibility runs from the Chief Executive of YSTHFT through the Corporate Board and CSCS Board Operational Management Structure to the SHYPS Director of Operations. The SHYPS Director of Operations acts across all sites and is responsible for all staff and aspects of service provision and organisation and is also the prime budget holder. Organisation Charts for SHYPS and the specific disciplines on the York & Scarborough sites can be found within [Appendix 1](#_Appendix_1:_Organisation) of this quality manual.

Responsibilities and accountabilities are defined in specific job descriptions. The responsibilities for Quality Management are defined in job descriptions and expanded in the document Quality Management Arrangements within SHYPS [SHY-INF-QMA]. Where practicable; key posts have identified deputies. In the absence of the Pathology Quality Manager the arrangements specified in the aforementioned [SHY-INF-QMA] will apply.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **SHYPS Pathology Group Director** | **SHY-INF-JOB-PGD** |
| **SHYPS Director of Operations** | **SHY-INF-JOB-DO** |
| **SHYPS Network Lead** | **SHY-INF-JOB-NL** |
| **SHYPS General Manager** | **SHY-INF-JOB-GM** |
| **SHYPS Training Manager** | **SHY-INF-JOB-TM** |
| **SHYPS Change and Innovation Manager** | **SHY-INF-JOB-CIM** |
| **SHYPS Quality Manager** | **SHY-INF-JOB-QM** |

Site discipline specific H&S Officers are responsible through their Laboratory Management Team to the Network Director of Operations who has ultimate responsibility for ensuring the Health, Safety and Welfare of staff and visitors within the laboratories.

Discipline specific Training Officers are responsible through their Laboratory Management Team to the Network Director of Operations who has ultimate responsibility for ensuring compliance with National and Trust training requirements.

All senior Biomedical Science staff must have proven technical and managerial competence appropriate to the post held. They must be registered with the HCPC and have relevant qualifications such as Licentiate, Member or Fellowship of the Institute of Biomedical Sciences (IBMS) or be HCPC registered Clinical Scientists

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

* It is the responsibility of all employees to become familiar with and participate in Quality Management and the requirements of the Quality Management System.
* Staff must at all times follow documented and approved SOPs.
* Staff must become familiar with the contents of this Quality Manual.
* Staff must complete a Corrective Action / Preventive Action (CA/PA) record on Q-Pulse in order that prompt and appropriate action can be taken to determine root cause and provide corrective action as soon as a nonconformity is identified. A risk assessment will be performed and the extent of harm assessed to ascertain if a DATIX is required to be raised for YSTHFT oversight.
* Staff must participate in annual appraisal.
* BMS staff must record self-assessments and Continuing Professional Development activities within their personal portfolios and ensure that their competency records are kept up to date.

#### 4.1.2.6. Communication

Policy for the management of YSTHFT is decided at Executive Board and devolved through the Care Groups. The main SHYPS management committees together with their Terms of Reference are documented in the SHYPS Governance Structure Policy [SHY-POL-GOVERN]. Specific action points are noted and assigned to specific staff together with an agreed timescale for implementation. Minutes of the meetings are taken and recorded on Q-Pulse as stipulated in the policy.

Staff meetings occur in laboratory areas and active participation by all staff is encouraged. These meetings also offer opportunities for staff to suggest changes and quality improvements (see also 4.14.4). Minutes of the meetings are taken, recorded on Q-Pulse, and distributed electronically to the staff via Q-Pulse.

The [Laboratory Medicine Website](https://www.yorkhospitals.nhs.uk/our-services/a-z-of-services/laboratory-medicine1/) contains links to all relevant information and the junior medical staff induction process communicates pre-examination requirements to stakeholders, to help ensure the effectiveness of examination, post examination processes and the quality management system. Where changes to examination procedures result in changes to reference ranges or differences in interpretation of results, users are informed in advance of the change.

In addition, there are regular opportunities for service user feedback on the effectiveness of the laboratory’s service via dedicated commissioner meetings, formal clinical rounds, YSTHFT leadership walk rounds, MDT participation and via periodic service user feedback surveys.

#### 4.1.2.7. Quality Manager

A Network Pathology Quality Manager has been appointed who reports to the SHYPS Governance Committee and has a line of accountability directly to the Network Director of Operations. The Quality Manager reports on the requirements of users determined though surveys, analysis of incident reports and consideration of complaints.

The Quality Manager ensures the continuing effective functioning of the QMS and is responsible for ensuring that policies and procedures are in place, records and information maintained and are available to ensure compliance with the required standards. The Quality Manager will develop policies and procedures in conjunction with the Senior Management Team.

## 4.2 Quality Management System (QMS)

### 4.2.1. General requirements

Through the creation of this Quality Manual laboratory management has provided documentary evidence of the existence of a QMS. The QMS consists of a series of processes, defined within this Quality Manual and illustrated in the Figure 2, which when executed in the correct sequence allows us to meet the requirements of our quality policy and to meet the needs and requirements of our users. Laboratory management will endeavour to improve the effectiveness of this QMS in accordance with the requirements of International Standard ISO 15189:2012. Processes are monitored and evaluated at the monthly SHYPS Quality Meeting. The Speciality has chosen Ideagen Q-Pulse Quality Management Software to help administer the QMS.

**ESTABLISHMENT** of the QMS is a*laboratory management responsibility*andevidence is provided by:

* Determining the needs and requirements of *users*
* Establishment of a *Quality Policy and Quality Manual*
* Setting *Quality Objectives*
* Defining responsibilities and authorities
* Establishing good internal communications
* Ensuring adequate resources
* Establishing service agreements where appropriate

**CONTROL** of the QMS is maintained by the*laboratory*by:

* Identifying and implementing the core and support *processe*s in the laboratory and determining their sequence and interaction
* Establishing *quality goals* and *performance specifications*
* Defining mechanisms for controlling process outcome and variation in terms of Quality Indicators and Operating Specifications
* Managing *resources*
* Controlling all documentation including procedures, instructions and forms
* Controlling support and process records

**REVIEW** of the QMS is a*laboratory management responsibility*andtakes place by:

* Conducting *Management Reviews* using the results of *evaluation* and *internal audit*

**IMPROVEMENT** of the QMS is carried out in the*laboratory*by:

* Instigating *Corrective Action*
* Conducting *Preventive Action*
* Having a commitment to *Continuous Improvement*

**Figure 2:** SHYPS Quality Management Cycle

### 4.2.2. Documentation requirements

#### 4.2.2.1 General

Hierarchy of the documentation system is shown below in Figure 3. The quality management system documentation includes statements of a quality policy [(4.1.2.3),](#page20) quality objectives [(4.1.2.4)](#page20) and a quality manual [(4.2.2.2).](#page24) Master electronic copies of documentation are held within the document module of Q-Pulse on the YSTHFT Q-Pulse. A full back up is performed daily. Documents accessed via Q-Pulse are presented to users in read only format to prevent unauthorised amendment and only active documents are available to users. Hard copies are available at the point of use, in addition to the electronic version for accessibility and ease. The location and number of hardcopies can be found within the Q-Pulse record and it is the responsibility of the person named to maintain them.

**Figure 3:** Hierarchy of the SHYPS Documentation System

#### 4.2.2.2 Quality Manual

This quality manual [LM-INF-QUALMAN] defines and describes the QMS in use. It references a copy of the SHYPS Quality Policy [SHY-POL-QUALITY] together with a statement of our aspirations regarding quality. The Quality Manual outlines the form of the Quality System in operation specifically on the SHYPS York & Scarborough hospital sites, identifying the general arrangements for ensuring that the quality policy is always adhered to by staff. The Quality Manual is reviewed regularly by the Quality Manager, approved by an independent member of the Senior Management Team and distributed to all staff who must acknowledge it electronically through the Q-Pulse document module thereby providing evidence of their awareness of the manual. Copies of applicable regulations, standards, policies, procedures, and records as required by ISO 15189: 2012 are retained within the Q-Pulse according to their function and referenced within the Quality Manual.

## 4.3 Document control

All documents that may vary based on changes in version or time are controlled by the QMS. The master list of all controlled documents is held within the Q-Pulse document module, which controls the document control process as represented diagrammatically in Figure 4*.* Full use is made of the facilities on Q-Pulse to ensure that the elements of 4.3 are met using the SHYPS Document Control Policy [SHY-POL-DOCS]. Documents of external origin, such as regulations, standards and textbooks from which examination procedures are taken are also considered and incorporated into the QMS in accordance with this procedure. Only the current, active versions of documents are available at point of use and theunintentional use of inactive and obsolete documents is prevented.

Records contain information from a particular point in time stating results achieved or providing evidence of activities performed and are maintained according to the requirements in 4.13 Control of records NOT document control as defined within this section. The Quality Manager is responsible for all aspects of the document control system.

**Document preparation and approval**

Prior to the introduction of the new document, the necessity for the introduction of the document must be considered. The training officer for the relevant discipline must be informed of any new procedures to allow departmental competencies to be reviewed. New controlled documents are prepared by relevant competent staff. These draft documents are reviewed and approved using the Q-Pulse approval process by the appropriate senior member of staff before issue. The responsibility for approval is normally that of the person in direct line management relationship to the author or reviser. It is essential that documents are approved in a timely fashion, documents held in the draft register for more than a month will be highlighted by the Quality Manager and a reminder issued to the document approver and owner.

**Document review**

Review does not imply revision. The purpose of reviewing a document is to ascertain its continuing ‘fitness for its intended purpose’. If it is still fit for purpose, the date of review and the reviewer is recorded in Q-Pulse and the document remains active (Figure 4, 6a). If the document is no longer fit for purpose, the document is withdrawn and becomes obsolete (Figure 4, 6b). Alternatively, it may be temporarily withdrawn and made inactive (Figure 4, 6c) or if it needs amendment, revision is undertaken and submitted for approval. It is the responsibility of senior laboratory 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 always done in practice. Q-Pulse provides alerts to document owners when a document is due for review. Documentation is reviewed on a biennial basis unless stipulated otherwise to comply with specific standards.

**Change and version control**

All documents and revisions are controlled via the Q-Pulse document module software. This laboratory does not permit the longhand amendment of hardcopies. Change requests must be made electronically through Q-Pulse where they will be reviewed by the document owner and incorporated as appropriate. Changes to existing documents are described on the ‘Document Revision History’ panel which is located on the front page of the document template – this information is also recorded within the ‘Change details’ of the specific document record on Q-Pulse.

**Document revision**

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

**Obsolete documents**

Obsolete documentation is retained for a specified time as defined in accordance with [LM-POL-RSDR] *Policy for the Retention, Storage and Disposal of Laboratory Records.*

## 4.4 Service Agreements

### 4.4.1 Establishment of Service Agreements

The SHYPS Senior Management Team will meet the requirement of ISO15189 regarding service agreements and work closely with YSTHFT Finance Department as documented in the Policy for the Establishment & Review of Service Level Agreements (SLA).

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **SHYPS Policy for the Establishment & Review of Service Level Agreements (SLA)** | **SHY-POL-SLA** |

To achieve this laboratory management will:

* Have a procedure for the establishment and review of any agreements for providing medical laboratory services.
* Ensure that agreements with non-NHS third parties are documented.
* Ensure that any formal service agreements are reviewed at an appropriate interval.

Laboratory Management will make agreements with non-NHS bodies for whom we provide laboratory services. All formal agreements will comply with the following processes:

1. Evaluation of the needs and requirements of the potential user to ensure they can be met.
2. Assessment of capability of the laboratory to meet the user’s requirements.
3. Documentation of the agreement and implementation.
4. Monitoring service delivered to the user.
5. Review after a pre-determined period set in the initial agreement.
6. Revision, if necessary, in conjunction with the user to return to stage 2 above.

Evidence of the procedure outcomes is given by copies of the SLAs in the Document Module of Q-Pulse under ‘Information’ and the relevant department.

**4.4.2 Review of Service Agreements**

As stated in 4.4.1, all formal agreements will be reviewed and revised as required under the control of Q-Pulse document module.

1. **EVALUATION** of the need for:

* A new document
* The addition of an external document

**2. PREPARATION** of a new **DRAFT** document with a unique informative filename

**4. APPROVAL** of a newdocument or a revised document

**3. VALIDATION** of a new **DRAFT** document or a revised document

**5. ISSUE** and **DISTRIBUTION** of a new or revised document

**REVIEW** of a current document for continuing suitability

**REVIEW** of a current document for continuing suitability

**THE DOCUMENT REGISTER**

Registration of a **DRAFT** document

Registration of an **ACTIVE** document

Registration of an **OBSOLETE** document

Registration of an **INACTIVE** document

6a

6b

6c

**Figure 4:** Document Control Procedure

## 4.5 Examination by Referral Laboratories

### 4.5.1 Selecting and Evaluating Referral Laboratories and Consultants

Referral facilities are only used:

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

Laboratory Management select and monitor the quality and competency of referral laboratories and consultants in accordance with the laboratory policy [SHY-POL-REFERRAL]*.* The policy objectives defined are addressed within specific departmental procedures.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Policy: Examination by Referral Laboratories** | **SHY-POL-REFERRAL** |
| **Biochemistry: Examination by Referral Laboratories** | **CB-SOP-REFERRAL** |
| **Haematology: Examination by Referral Laboratories** | **HA-SOP-REFERRAL** |
| **Haematology: Table of SAS Laboratories & Repertoires** | **HA-INF-SAS** |
| **Transfusion: Referring samples for send-away tests** | **BT-SOP-REFERRAL** |
| **Microbiology: Selection, Review and Evaluation of Reference Laboratories** | **MB-SOP-REC-SEND** |
| **Microbiology: Referral Laboratory Addresses** | **MB-SOP-REC-REFLAB** |
| **Microbiology: Reporting of Reference Laboratory Results** | **MB-SOP-REFREPORT** |
| **Histology: Consultant Referrals** | **HI-INF-CON REF** |
| **Histology: Amending Histopathology Reports** | **HO-SOP-AMNDRPT** |

Wherever possible samples are referred only to laboratories that are UKAS accredited, if the referral laboratory is not listed as ‘Accredited’ on the UKAS website, they are requested to produce documentary evidence to demonstrate continued suitable EQA performance for the assay(s) being undertaken. Accreditation status of referral centres are checked against the UKAS website to ensure continuing compliance against their standards. In addition, turnaround times produced by referral centres and costs are checked. A list of referral laboratories and consultants used for each department is maintained and available on the Laboratory Medicine Website for users.

All departmental procedures adhere to current UN 3373 regulations for the transportation of samples and provide evidence of traceability of all portions of the primary sample to the original sample, including a record of all samples referred and their dispatch dates.

### 4.5.2 Provision of Examination Results

SHYPS (as the referring laboratory) retains responsibility for ensuring that the results of tests undertaken by referral laboratories are provided to the test requester and a record of these results are retained.

Discipline specific procedures must ensure referral tests undertaken are clearly identified as having been generated by the referral laboratory or referral consultant on the report issued to the test requester and includes all essential elements of the results reported by the referral laboratory. The author of any additional comments will be clearly identified.

The discipline specific procedure adopted to report referral laboratory results shall consider turnaround times, measurement accuracy, transcription processes and interpretative skill requirements.

## 4.6 External Services and supplies

The general policies and procedures for the selection and purchasing of external services, equipment, reagents, and consumable supplies are governed by those of YSTHFT. These policies and procedures inform the SHYPS documentation:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **SHYPS Policy- Selection and Purchasing of External Services, Equipment, Reagents and Consumables** | **SHY-POL-SUPPLIES** |
| **SHYPS Procedure for Selection & Monitoring Suppliers** | **SHY-SOP-SUPPLIERS** |

A list of selected and approved suppliers of equipment, reagents and consumables is maintained by the Trust Purchasing Department using the Oracle Catalogue. Items required which are not on the catalogue must have approval from the Medical and Surgical Supplies and Equipment Committee.

Suppliers are monitored to ensure that purchased services or items consistently meet the stated criteria which may be included as part of a managed service contract. If a supplier is not performing to agreed standards (via SLA or contract) the Purchasing Department would be required to be informed and meetings with said suppliers initiated to enable an agreement/arrangement to be reached.

The performance of suppliers is monitored using the Q-Pulse Suppliers module. The performance of suppliers is discussed at Senior Management Team Meetings and any issues are formally reviewed by inclusion in the Annual Management Review.

## 4.7 Advisory Services

Information for all service users is initially communicated through the official YSTHFT website, A-

Z of Services which includes Laboratory Medicine/Pathology:

[**York Hospitals Website**](https://www.yorkhospitals.nhs.uk/our-services/a-z-of-services/laboratory-medicine1/)

This resource contains a plethora of information including key contacts for each discipline, sample requirements, clinical indications and limitations of examination procedures and the frequency of requesting the examination (see 5.4).

More specific advice on the choice of examinations, individual cases, and the interpretation of results of examinations is available to meet the needs and requirements of users, firstly by the inclusion of automatic comments on reports, secondly by the inclusion of comments in the report added manually by the clinical staff and thirdly users can seek further clarification by contacting the clinical staff using the telephone numbers listed on the YSTHFT web site. Such staff are always available to discuss results with clinical colleagues.

Comments on reports are clear, succinct, and unambiguous. Only authorised personnel with appropriate training provide clinical advice and interpretive comments. Clinical staff are also available to assist users to obtain the most effective utilisation of the laboratory service. Laboratory staff are also able to offer advice to assist with the correction of specific problems that may be experienced by users, such as instances of sample rejection due to a failure to meet laboratory acceptance criteria.

## 4.8 Resolution of complaints

It is Trust policy that dissatisfied service users should be encouraged to tell their concerns when they arise. Whenever possible, their concerns should be handled by the department or area in contact with them. Staff must offer reassurance and respond to matters of concern as they arise.

Pathology has in place a documented procedure for the management of complaints from clinicians, patients, laboratory staff and other parties.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **The Handling of complaints in Laboratory Medicine** | **LM-SOP-COMPLAINT** |

If these attempts to resolve concerns fail; the YSTHFT Patient Advice and Liaison Service (PALS) will try to facilitate an appropriate and acceptable resolution in accordance with the YSTHFT Concerns and Complaints Policy and Procedure [YT-POL-COMPLAINT]. A person may make the complaint directly to PALS or the Patient Experience Team (PET).

The laboratory investigates all complaints received. All complaints are discussed at Senior Management Team Meetings, including the Governance Committee and departmental staff meetings as relevant and appropriate to the complaint. A Q-Pulse CAPA record is generated of the complaint and of the actions taken by the laboratory in response. This record is maintained locally in Q-Pulse, allowing all complaints to be reviewed at the annual management review meeting. A record is also maintained centrally within the YSTHFT Datix system. (See also 4.14.3)

## 4.9 Identification and Control of Nonconformities

Laboratory Management will ensure that the requirements of ISO 15189 are met about identification and control of non-conformities in any aspect of the quality management system including pre-examination, examination, or post-examination processes. This is led by the Policy for continual improvement [SHY-POL-QUAL IMP] which details the departmental procedures which:

* Designates the responsibilities and authorities for handling non-conformities.
* Defines immediate actions to be taken.
* Ensures the extent of the non-conformity is defined.
* Ensures examinations are halted and reports withheld as necessary.
* Ensures the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorised individual responsible for using the results is informed.
* Ensures the result of any nonconforming examinations already released are recalled or appropriately identified, as necessary.
* Ensures the responsibility for authorisation of the resumption of examinations is defined.

The nonconformities are documented and recorded within the Q - Pulse CAPA module according to the SHYPS SOP for Managing Nonconformities in the Q-Pulse CAPA Module [SHY-SOP-QP-CAPA]. Nonconformities are discussed departmentally. In addition, the CAPA records are reviewed by the Network Pathology Quality Manager to detect trends and suggest any further corrective action at the monthly Network Quality Meeting. Non-conformities are included as part of the Annual Management Review.

Nonconformities concerning results are prevented and managed according to the specific technical requirements of ISO 15189: 2012, notably: [5.6 Ensuring Quality of Examination Results;](#page63) [5.7 Post –](#page67) [Examination Processes;](#page67) [5.9 Release of Results.](#page69)

## 4.10 Corrective Action

Laboratory Management will ensure that the requirements of ISO 15189 are met regarding corrective action. The systems and procedures used by the laboratory to identify and control non-conformities, described in section 4.9, ensure where appropriate an investigative process to determine the root cause of the problem is in place. Each discipline evaluates the need for corrective action to eliminate the causes of non-conformities recorded as Datix incidents, complaints, IQC, IQA, EQAS and equipment downtime to ensure non-conformities do not recur. The nature of the corrective action depends on the classification of the non-conformity and on the magnitude of the risk to the patient.

Corrective action is facilitated using the CAPA module in Q-Pulse following the SOP for Managing Nonconformities in the Q-Pulse CAPA Module [SHY-SOP-QP-CAPA]. Target dates for processing and closing off non-conformances are pre-set depending on the CAPA template assigned for the non-conformance but are usually to be complete within 60 days. The exception is equipment downtime errors which are pre-set at 7 days.

However, if it is acknowledged that a non-conformance may take longer than its’ pre-set target date to complete in order to provide a thorough and appropriate corrective action, in these cases the target date is amended accordingly documenting the reason in the notes for the CAPA.

This module ensures the compliance with the following areas of ISO 15189:

* Review of non-conformities.
* Determining the root causes of non-conformities.
* Evaluating the need for corrective action to ensure the nonconformities do not recur.
* Implementing corrective action.
* Recording the results taken.
* Reviewing the effectiveness of the corrective action.

Laboratory Management ensure that corrective actions taken are effective by periodic review of the incidents, trend analysis and the use of internal audit. Such reviews are incorporated into departmental staff meetings, the monthly Quality Meetings and the Annual Management Review.

## 4.11 Preventive Action

Preventive actions are firmly embedded within the QMS. Examples include:

* Training.
* Risk Assessment.
* H&S inspection.
* Performance of quality audits.
* Equipment maintenance & Calibration.
* Internal QC & QA.
* External Quality Assessment (EQA).
* Communication meetings.

Preventive action is facilitated using the CAPA module in Q-Pulse following the laboratory SOP for Managing Nonconformities in the Q-Pulse CAPA Module [SHY-SOP-QP-CAPA]. Target dates for processing and closing off non-conformances are pre-set depending on the CAPA template assigned for the non-conformance but are usually to be complete within 60 days. However, if it is acknowledged that a non-conformance will take longer than its’ pre-set target date to complete the target date is amended accordingly documenting the reason in the notes for the CAPA.

This module ensures the compliance with the following areas of ISO 15189:

* Review of non-conformities.
* Determining the root causes of non-conformities.
* Evaluating the need for preventive action to ensure the non-conformities do not recur.
* Implementing preventive action.
* Recording the results taken.
* Reviewing the effectiveness of the preventive action.

Laboratory Management ensure by review that preventive actions taken are effective by periodic review of the incidents, trend analysis and the use of internal audit. Such reviews are incorporated into departmental staff meetings, the monthly Quality Meeting and the Annual Management Review.

## 4.12 Continual Improvement

The Policy for Continual Quality Improvement [SHY-POL-QUAL IMP] illustrates how quality improvements can be recognised and ensures that the requirements of ISO 15189 are met regarding continual improvement. To achieve this, it will

* Use management reviews to compare the laboratory’s actual performance in its evaluation activities, corrective actions, and preventive actions with its intentions, as stated in the quality policy and quality objectives.
* Direct improvement activities at areas of highest priority based on risk assessments.
* Develop action plans which will be implemented and documented as appropriate.
* Effectiveness of actions shall be assessed through regular review.
* Ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.
* Address any opportunities for improvement regardless of where they occur.
* Communicate to staff improvement plans and related goals.

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| **Document References** | **Q-Pulse Reference** |
| **Policy for Continual Quality Improvement** | **SHY-POL-QUAL IMP** |

## 4.13 Control of Records

The laboratory aims to comply with the national guidance document ‘*the retention and storage of* *pathological records and specimens’* as co-authored by the Royal College of Pathologists (RCPath)and the Institute of Biomedical Science (IBMS) [LM-INF-RCPTH ARC] and operates under the guidance of the Trust Records Management policy [YT-POL-RECORD] and Records Management Policy Retention Schedule [YT-INF-RECORD RET].

These documents have informed the laboratory Policy for the Retention, Storage and Disposal of Laboratory Records [LM-POL-RSDR] which describes how the Speciality complies with ISO 15189 for the records as required below in this sub-clause and gives reference to procedures which describe particularly how process and quality records are stored departmentally:

1. Supplier selection and performance, and changes to the approved supplier list.
2. Staff qualifications, training, and competency records.
3. Request for examination.
4. Records of receipt of samples in the laboratory.
5. Information on reagents and materials used for examinations (e.g., lot documentation, certificates of supplies, package inserts).
6. Laboratory workbooks or work sheets.
7. Instrument printouts and retained data and information.
8. Examination results and reports.
9. Instrument maintenance records, including internal and external calibration records.
10. Calibration functions and conversion factors.
11. Quality control records.
12. Incident records and action taken.
13. Accident records and action taken.
14. Risk management records.
15. Nonconformities identified and immediate or corrective action taken.
16. Preventive action taken.
17. Complaints and action taken.
18. Records of internal and external audits.
19. Interlaboratory comparisons of examination results.
20. Records of quality improvement activities.
21. Minutes of meetings that record decisions made about the laboratory’s quality management activities.
22. Records of management reviews.

## 4.14 Evaluation and audits

### 4.14.1 General

The laboratory uses internal audit to provide evidence that pre-examination, examination, and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users and the QMS is conformed to across all departments.

The Quality Manager creates a planned programme of audits annually within the Q-Pulse audit module to assess departmental compliance with each of the ISO 15189 sub-clauses. A series of vertical, horizontal and examination audit templates have been devised which are viewable in the audit module of Q-Pulse. Full use is made of the facilities on Q-Pulse to ensure that the audits are implemented, and the findings recorded, non-conformities acted on and available for review to continually improve the effectiveness of the QMS. Non-conformities or deficiencies found on audit are recorded in the audit module of Q-Pulse, which automatically feeds through to the CAPA module. All non-conformances have defined target dates which are generated when the CAPA is raised.

The internal audit programme is carried out by the staff who have sufficient knowledge in the area being audited, have received audit training by the Quality Management Team and assessed as competent in the task. Auditors will, wherever possible, be independent of the laboratory area being audited to provide objectivity and impartiality, however, this is not always possible, and objectivity is maintained by providing a specific list of audit questions.

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| **Document References** | **Q-Pulse Reference** |
| **Use of the Q-Pulse Audit Module** | **SHY-SOP-QP-AUDIT** |

The results of internal audit are evaluated, and the decisions taken documented, monitored, and reviewed at departmental meetings as appropriate to be discussed at the monthly Quality Meeting in a format to allow inclusion in the annual management review.

### 4.14.2 Periodic Review of Requests, and Suitability of Procedures and Sample Requirements

Authorized personnel periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. Reverification takes place at every 2 years and is prompted by the review of the original examination procedure performed.

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| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy for Validation and Verification** | **LM-POL-VALIDATE** |

The laboratory periodically reviews its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue, and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected, and the sample is properly collected to preserve the measurand.

The review of the above takes place within the specialities and is reported to the SHYPS Governance Committee in a format to allow inclusion in the annual management review.

The Laboratory Website includes this information for the users. At times of review, discipline specific senior staff are advised that review is underway and are expected to review information pertaining to their own areas; this includes sample volumes, collection device and preservative requirements.

### 4.14.3 Assessment of User Feedback

[See 4.1.2.2 Needs of users](#page19)

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| **Document References** | **Q-Pulse Reference** |
| **Procedure for Recording of Feedback from Users** | **LM-SOP-USER FEEDBACK** |

### 4.14.4 Staff Suggestions

The laboratory is committed to ensuring that staff feel suitably empowered to make suggestions for quality improvement. Staff can make these suggestions via:

* Departmental meetings [(see 4.1.2.6. Communication)](#page21)
* One to one discussion with senior staff.
* Directly to their manager via the Q-Pulse CAPA Module facilitated by the shortcut from the Launchpad as described in the procedure, Q-Pulse Introduction & Basic Use or via paper format.

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| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Quality Improvement Notice** | **LM-TEM-QIN** |
| **Q-Pulse Introduction & Basic Use** | **SHY-SOP-QP-BASIC USE** |
| **SHYPS Change Control Management Policy** | **SHY-POL-COC** |
| **Managing Nonconformances in the Q-Pulse CAPA Module** | **SHY-SOP-QP-CAPA** |
| **Laboratory Procedure for Recording Quality Improvement Recommendations** | **SHY-SOP-QUAL IMP** |



Records of suggestions made, evaluation, feedback given, and action taken by the management are maintained by the SHYPS Change Control Management Policy [SHY-POL-COC].

All standard operating procedures are reviewed regularly as per the requirements of the document control system [(4.3)](#page24) to ensure the accuracy of the content and as an opportunity to identify potential sources of improvement in quality management or technical practices. All staff have the ability and access to suggested changes via the change request facility within the Q-Pulse Document Module which enables the reviewer of the change request to respond to the individual member of staff who raised the request.

### 4.14.5 Internal Audit

See [4.14.1 General](#page33)

### 4.14.6 Risk Management

A comprehensive risk assessment process is in place which considers risk to service provision and patient safety as well as to health and safety associated risks.

The impact of work processes and potential failures on examination results as they affect patient safety are evaluated and reference given in laboratory Standard Operating Procedures. Modifications to reduce or eliminate the identified risks are documented within the referenced risk assessments retained in the Q-Pulse Document Module.

All non-conformities including adverse incidents, concerning SHYPS are encouraged to be reported by staff in the Q-Pulse CAPA module to enable effective management of pursuant corrective actions including timely amendment of work processes according to the SHYPS Policy for Continual Improvement [SHY-POL-QUAL IMP]. The CAPA Module can be considered the central repository for all nonconformities to allow trends to be identified across the Network. Depending on the incident incidents may also be required to be simultaneously recorded using the YSTHFT Datix Software YSTHFT Incident Management Policy [YT-POL-AIRS] and are. All DATIX incidents are reviewed monthly by the Quality Manager and trends reported to the SHYPS Governance Committee in a format that can then be presented at the Management Review.

Any significant or high risks are recorded on the Laboratory Risk Register in accordance with YSTHFT Risk Management Framework [YT-POL-RISK MAN] and the SHYPS Risk Management Policy [SHY-POL-RISK]. The Register is discussed monthly at SHYPS Governance Committee and within the Care Group Quality & Safety meetings to raise awareness of our current risks.

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| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| YSTHFT Risk Management Framework | YT-POL-RISK MAN |
| **SHYPS Risk Management Policy** | **SHY-POL-RISK** |
| **Policy for Continual Quality Improvement** | **SHY-POL-QUAL IMP** |
| **Procedure for Conducting Risk Assessments (Inc. COSHH)** | **LM-SOP-RISKASS** |

### 4.14.7 Quality Indicators

The laboratory has established several quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination, and post-examination processes. The process of monitoring quality indicators is planned, and includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. The indicators are periodically reviewed to ensure their continued appropriateness.

The laboratory complies with the NHSEI requirements to submit key performance indicators monthly to the Pathology Quality and Assurance Dashboard (PQAD).

The Quality Manager attends the required Care Group Governance Meeting and presents the dashboard (PQAD). Items reviewed include risk register, key turnaround times (e.g., results reported to Emergency Department), Adverse Incidents (DATIX), Serious Incidents (SI) and formal complaints.

All disciplines have a minimum set of quality indicators, which may include:

* Number of acceptable samples.
* Number of errors at specimen reception.
* Number of amended reports.
* Expected turnaround times.

To ensure turnaround times are as short as possible without compromising quality of results for all assays these will be regularly monitored and results compared to turnaround times stated in the laboratory handbook. Where turnaround times fall outside these defined limits, every effort will be taken to ensure they are rectified. Turnaround times are regularly discussed at discipline specific staff meetings.

Pre-analytical turnaround times are also monitored to ensure acceptable transportation times and to account for delays between arrival in the laboratory and booking requests into the laboratory system.

For a description of the indicators in use and the means of the means of evaluation please see the documentation listed below:

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| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy for Quality Indicators** | **LM-POL-QUAL IND** |

Quality Indicators are discussed at discipline specific staff meetings and reported to the monthly Governance Committee meeting. Quality indicators are reviewed as part of the Management Review.

### 4.14.8 Reviews by External Organisations

Reviews of the laboratory service by external organisations are recorded in the Audit module of Q-Pulse. Non-conformities or deficiencies found during the review are raised within the audit module which automatically feeds through to the CAPA module for subsequent action. The reviews from external organisations are reported by the Quality Manager to the Monthly Governance Committee Meeting and other meetings within the Speciality as deemed relevant and incorporated into the Annual Management Review.

See [4.14.1 General](#page33)

[See 4.10 Corrective Action](#page30)

[See 4.11 Preventive Action](#page31)

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

* United Kingdom Accreditation Service (UKAS).
* Care Quality Commission (CQC).
* Health & Safety Executive (HSE).
* Medicines and Healthcare products Regulatory Agency (MHRA).
* Human Tissue Authority (HTA).
* Screening Quality Assurance Service (SQAS).

## 4.15 Management Review

### 4.15.1 General

The Pathology Quality Manager reviews the QMS on an annual basis to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

The review elements include:

[Review input (4.15.2)](#page37)

[Review activities (4.15.3)](#page38)

[Review output (4.15.4)](#page38)

|  |  |
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| **Document References** | **Q-Pulse Reference** |
| **SHYPS Policy for Management Review** | **SHY-POL-MAN REV** |

### 4.15.2 Review input

The review includes information from the results of the following evaluations:

* The periodic review of requests, and suitability of procedures and sample requirements (see [4.14.2)](#page34)
* Assessment of user feedback (see [4.14.3)](#page34)
* Staff suggestions (see [4.14.4](#page34))
* Internal Audits (see [4.14.5)](#page35)
* Risk Management (see [4.14.6)](#page35)
* Use of quality indicators and the appropriateness of these in terms of assessing the laboratory’s contribution to patient care (see [4.14.7](#page35))
* Reviews by external organizations (see [4.14.8)](#page36)
* Results of participation in inter-laboratory comparison programs including EQA performance (see [5.6.3)](#page65)
* Monitoring and resolution of complaints (see [4.8)](#page29)
* Performance of suppliers (see [4.6)](#page28)
* Identification and control of nonconformities including the causes of nonconformities and patterns or trends which highlight potential process problems (see [4.9](#page30))
* Results of continual improvement (see [4.12](#page32)) including current status of corrective actions (see [4.10](#page30)) and preventive actions (see [4.11](#page31))
* Follow-up actions from previous management reviews
* Changes in the volume and scope of work, personnel, and premises that could affect theQMS
* Recommendations for improvement to the QMS, including the impact upon the quality policy (see [4.1.2.3](#page20)) and technical requirements
* Review of on-going staffing levels, training and education programs (see [5.1.1,](#page38) [5.1.5,](#page40) [5.1.8)](#page42).

### 4.15.3 Review Activities

The review is based on the factual analysis of the input data to ensure effective decisions are made.

The review assesses opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

The quality and appropriateness of the laboratory’s contribution to patient care, to the extent possible, is objectively evaluated.

### 4.15.4 Review Output

The findings and actions of the review are formally documented as minutes and submitted for approval by the Senior Management Team. Relevant information from the Management Review will be discussed and disseminated with the teams in appropriate departmental meetings.

# 5.0 Technical Requirements

## 5.1 Personnel

### 5.1.1 General

Personnel Management is carried out under the Recruitment, Selection and Appointment Policy: [YT-POL-RECRUIT] of the Human Resources Department at YSTHFT. Recruitment, Selection and Appointment – Additional Guidance for Managers [YT-INF-RECRUIT] is available on the Trust Intranet site Staff Room.

Staff members are registered in accordance with current national legislation and guidelines. YSTHFT Human Resources department checks the registration status of all posts which require registration; the doctors must show their GMC renewals to the Governance Manager in accordance with the Trust Policy ‘Maintaining Processional Registration Guidance’ [YT-POL-PROF REG]. A HCPC registration check of credentials is performed prior to the employment of Clinical Scientists and Biomedical Scientists. An annual staff HCPC registration check is also performed by the YSTHFT and the Quality Manager [SHY-AUD-HCPC CHK].

The nature and number of staff required by the SHYPS is kept constantly under review (see [Review input (4.15.2),](#page37) specialty and senior management team meetings) as new working practices and organisation structures are developed. Indirect evidence of inappropriately low staffing levels may include the number of meetings cancelled, decisions recorded but not acted upon and staff performance reviews behind schedule. Direct evidence would be from quality indicators targeted at pre-examination, examination, and post examination performance. The decision of whether a person can be replaced, or a new post created is subject to the stringent YSTHFT vacancy control procedures.

### 5.1.2 Personnel Qualifications

A job description and personnel specification set out the personnel qualifications required for each post. The qualifications reflect the appropriate education, training, experience and demonstrated skills appropriate and needed for the tasks performed in the job description. NHS Agenda for Change job evaluation and matching determines the specific forms of qualification and/or years of experience required for NHS jobs. These qualifications are set in accordance with national regulations determined by NHS Agenda for Change job matching and evaluation and partly by the job assessment of Laboratory Management. Staff qualifications are scrutinised as part of the recruitment process and copies are stored electronically on the trac.jobs Application Management System. Examples of department job descriptions & person specifications are available within the document module of Q-Pulse for reference.

### 5.1.3 Job Descriptions

Each member of staff has a unique job description that includes:

* Job title.
* The location within the organisation.
* Accountability.
* The main purpose of the job.
* The main duties and responsibilities.
* A requirement to participate in personal development review (PDR).

Staff are provided with a hardcopy of their job description. Contracts are kept in hard copy only in locked filing cabinets accessible by the office staff of the York Laboratory or in the Laboratory Office at Scarborough.

### 5.1.4 Personnel Introduction to the Organizational Environment

Staff induction consists of two elements within the laboratories.

Newly employed staff must be enrolled on the corporate induction programme, which gives an overview of YSTHFT in accordance with the Trust Training Identification Guidelines (Corporate Statutory Mandatory) [YT-INF-STAT MAN]. Staffs must also receive specific local induction.

Staff induction gives information on:

* The individual departments, Pathology in general, and YSTHFT.
* Terms and conditions of employment.
* Patient confidentiality and data protection.
* Health & safety including fire and emergency.
* Occupational health services.
* Job description and organisational charts.
* Salaries and wages.
* Staff facilities.

Department specific inductions are described in the Q-Pulse documentation listed below:

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| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Clinical Biochemistry: Induction Document** | **CB-INF-INDUCTION** |
| **Blood Sciences Reception MLA: Induction Document** | **SR-INF-INDUCTION** |
| **Haematology, Immunology, Blood Transfusion: Induction Document** | **HA-INF-INDUCTION** |
| **Histopathology: Induction Document** | **HI-INF-INDUCTION** |
| **Microbiology: Induction Document** | **MB-INF-INDUCTION** |
| **POCT: Induction Document** | **PC-INF-INDUCTION** |



The laboratory has a training policy which states its commitment to providing continuing training and education for all members of staff. The policy states that personnel undergoing training shall be always supervised. The effectiveness of the training programme is kept constantly under review at Training Officer, Specialty and Senior Management Team Meetings as new working practices and organizational structures are developed and included in the Annual Management Review (see [4.15.2](#page37))

The Training Officers within each department ensure that all staff attends the training deemed mandatory by the YSTHFT. All unregistered BMS staff attend approved courses to attain Health Professions Council, (HCPC), registration and eligibility to become at least licentiates of the Institute of Biomedical Sciences, (IBMS). MLAs are encouraged to engage in NVQ courses.

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| **Document References** | **Q-Pulse Reference** |
| **SHYPS Training Policy** | **LM-POL-TRAINING** |

Pathology provides training for all personnel which include the following areas:

1. The Quality Management System: All new starters receive an introductory presentation covering the Quality Management System within Pathology, which is hosted on the YSTHFT e-Learning Hub. The Quality Manager gives individual training on Q-Pulse as relevant to the staff member’s role on a one-to-one basis.
2. Assigned work processes and procedures: The training programme for core work processes and procedures are set down in the Training Manuals for each department. These documents are available on Q-Pulse:

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| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Clinical Biochemistry Training Manual** | **CB-INF-TRAINING** |
| **Clinical Biochemistry MLA/Clerical Training Manual** | **SR-INF-TRAINMAN** |
| **Cytology Training Manual** | **CY-INF-TRAINMAN** |
| **Haematology Training Manual** | **HA-INF-TRAINMAN** |
| **Histopathology Training Manual** | **HI-INF-TRAINMAN** |
| **Microbiology Training Manual** | **MB-INF-TRAINING** |
| **POCT Training Manual** | **PC-INF-TRAINMAN** |

1. The applicable laboratory Information System: The Laboratory IT Systems Manager and nominated discipline specific IT coordinators have the authority to assign Telepath log-ins. An overview of Telepath and departmental processes are taught as part of the training programme.
2. Health & Safety: Health & Safety is a part of the Trust Corporate Statutory and Mandatory training programme at induction and updated every 3 years through the YSTHFT e-Learning Hub. Further departmentally related training is conducted within the departments. A generic laboratory Health & Safety Presentation is presented by the Laboratory Trust Health & Safety representative or departmental representative at induction which is available on Q-Pulse [LM-INF-H & S INDUCT].
3. Ethics and f) Confidentiality of patient information: These areas are incorporated into the Trust Corporate Statutory and Mandatory training programme at induction and as an annual update.

### 5.1.6 Competency Assessment

Within Pathology competence assessment is focused on confirming the ability of an employee to perform specific tasks in accordance with approved Standard Operating Procedures.

**Competency is assessed by using the following approaches under the same conditions as the working environment:**

1. Written Assessment e.g., Q & A.
2. Direct Observation of routine work processes & procedures, including all applicable safety practices.
3. Direct Observation of equipment maintenance and function
4. D: Review of work records
5. Examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples.
6. Assessment of problem-solving skills.

The ‘Template for Competency Assessment’ [LM-TEM-CA] has been developed to create generic Laboratory and discipline specific task-based competencies. The ‘Template for questions and evidence to support competency assessment’ [LM-TEM-COMP-KNOW] is also available.

During training, staffs are assessed against these criteria and a hardcopy record of the competency assessment is signed. Retraining and actions required are determined as required. The event (competency assessment) may be recorded in the Q-Pulse Training Module, however; experience has proved this system to be unwieldy and as such signed hardcopy records of competency assessments are still maintained by staff in their personal training files as the primary record of competency. Competency is reviewed as appropriate (commonly 2 years).

Competency assessment for professional judgement regarding clinical competency is specifically designed as detailed in the document: LM-SOP-MED COMP - Medical Staff Competencies.

### 5.1.7 Reviews of Staff Performance

All SHYPS staff partakes in an Annual Joint Review or Personal Development Review (PDR) in line with the YSTHFT Appraisal Guidance [YT-POL-APPRAISAL]. PDR takes into consideration:

1. The stated objectives and plans of the YSTHFT and the laboratory.
2. The job description of the member of staff.
3. The personal objectives of the staff member.
4. The training and development need of the staff member.

The staffs performing the PDR receive in-house training from YSTHFT which is recorded in the Q-Pulse training module (see 5.1.7 Competency Assessment).

PDR is managed through use of the YSTHFT Learning Hub all records of the PDR are maintained within the Learning Hub to ensure confidentiality is maintained between appraiser and appraisee. The objectives, (PDPs or Personal Development Plans), however, are not confidential as these are required for training needs analysis.

### 5.1.8 Continuing Education and Professional Development

To remain registered with the Health and Care Professions Council (HCPC) staff must undertake continuing professional development (CPD) activities and keep a record of them. Pathology have a documented policy:

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| **Document References** | **Q-Pulse Reference** |
| **Continuing Professional Development Policy** | **LM-POL-CPD** |

Staff should keep a personal portfolio to capture all the CPD activities undertaken. The evidence held should satisfy the various political, professional, and legal requirements. All staff are issued with training files in which to keep this information.

Educational and training resources include:

1. Access to the Trust library and on-line resources via the Trust Intranet and Internet facilities. Journals relevant to each discipline are kept in the offices of the consultants in that discipline.
2. York has its own seminar room, and a training room is available on the Scarborough site, video conferencing facilities are available for virtual meetings and training sessions. Access to a quiet room for study is also available departmentally.
3. Staffs are encouraged to attend instrument training courses, user group meetings, symposia, and conferences.
4. Financial support is given to staff, within the budgetary constraints.

### 5.1.9 Personnel Records

Personnel records are kept in hard copy format only in personal files within locked filing cabinets accessible by the main office team on the first floor of the York Laboratory or in the Laboratory Office at Scarborough. Access is restricted to those with the appropriate authority. Some of the records explicitly referred to in ISO 15189 may also be held externally within the Trust according to the laboratory Policy.

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| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy for the Retention, Storage and Disposal of Laboratory Records** | **LM-POL-RSDR** |

## 5.2 Accommodation and Environmental Conditions

### 5.2.1 General

Laboratory Management allocates space for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patient and visitors in accordance with national legislation and guidelines.

Working space is a resource and internal space is reconfigured as necessary to meet requirements. The premises and space issues are discussed at departmental and Speciality meetings and reviewed at the Annual Management Review (see [4.15.2](#page37)). If insufficient working space is highlighted it is incorporated onto the Risk Register.

A general risk assessment of the environment within the York & Scarborough laboratories is carried out 2 yearly as a minimum in each discipline according to the following laboratory procedure. The final Risk Assessment document is embedded into Q-Pulse. Each discipline on each site also carries out regular Health and Safety Inspections, as often as local protocol dictates, currently on a quarterly basis and no less than twice a year. According to the laboratory Safety Policy, checks include (but are not limited to) chemical/COSHH, electrical/mechanical, fire safety, first aid, fume cupboards, general, PPE and waste disposal, etc.

Evidence of these inspections are retained within the Health & Safety section of the Q-Pulse Audit Module. Any non-conformances are recorded in the CA/PA module of Q-Pulse to ensure action is taken to rectify them.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Procedure for Conducting Risk Assessments (Inc. COSHH)** | **LM-SOP-RISKASS** |
| **Undertaking A Health and Safety Inspection** | **LM-SOP-HSINSP** |
| **Laboratory Medicine Safety Policy** | **LM-POL-SAFETY** |
| **Laboratory Medicine Security** | **LM-POL-SECURITY** |
| **Local Rules** | **LM-POL-LOCAL** |

Where applicable, similar provisions are made for examinations at sites other than the main laboratory premises, for example point of care testing (POCT) under the management of the laboratory. Remote areas are risk assessed and checked quarterly by the POCT staff. Evidence of these checked are maintained within the Health & Safety section of the Q-Pulse Audit Module.

### 5.2.2 Laboratory and Office Facilities

Pathology management as detailed above has policies and procedures in place which ensure the laboratory and associated office facilities provide an environment suitable for the tasks undertaken, by ensuring the following conditions are met:

* Access to areas affecting the quality of examinations is controlled.
* Medical information, patient samples, laboratory resources are safeguarded from unauthorised access.
* Facilities for examination allow for correct performance of examinations. These include, for example lighting, ventilation, noise, water, and environmental conditions.
* Safety facilities and devices are provided, and their functioning regularly verified, for example, operation of emergency release, alarm systems for blood transfusion fridges.
* Where necessary, SOPs contain relevant information and instruction such that staffs are aware of risks and, through the competency system in force, are deemed competent to manage these risks. Supplementary to this, safety notices are posted within the department to reinforce the message regarding such hazards as electricity, high and low temperatures, inflammables, ionising radiation etc.
* Communication systems within pathology are appropriate to ensure efficient transfer of information.

Wherever possible communications systems utilise electronic means, e.g., supplying information on intranet or internet to avoid making phone calls and electronic requesting/reporting, which, evidenced by survey results, is very popular with users.

### 5.2.3 Storage Facilities

The laboratory aims to comply with the national guidance document *The retention and storage of* *pathological records and specimens* as co-authored by the Royal College of Pathologists (RCPath)and the Institute of Biomedical Science (IBMS) and operates under the guidance of the Trust Records Management policy [YT-POL-RECORD] and Records Management Policy Retention Schedule [YT-INF-RECORD RET].

These documents have informed:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **The Laboratory Medicine Policy for the Retention, Storage and Disposal of Laboratory Records** | **LM-POL-RSDR** |
| **Policy for the Retention, Storage and Disposal of Laboratory Samples** | **LM-POL-RSDS** |

[LM-POL-RSDR] describes how the laboratories complies with ISO 15189 for the records specified in the sub-clause 4.13 Control of Records and gives reference to procedures which describe particularly how process and quality records are stored departmentally.

[LM-POL-RSDS] describes how the laboratories complies with ISO 15189 for the storage of clinical samples in the sub-clause 5.7.2 Storage, retention, and disposal of clinical samples.

* Clinical material is stored in separate facilities appropriate to the specific material. Temperatures are controlled, monitored, and recorded as necessary.
* Blood and blood products are stored in refrigerators specific to the task. Temperatures are controlled, monitored, and recorded as necessary.
* Hazardous substances are stored variously according to type in solvent/acid/alkali bins, extraction cabinets and/or locked & restricted access cupboards. Large volumes of hazardous material are stored in purpose-built stores isolated from the main building.
* No drugs, vaccines or therapeutics are stored within the departments of Cytology, Histology or Microbiology. Materials of this type in Haematology are stored in a separate area of the Blood Transfusion refrigerated storage. Clinical Biochemistry also uses the facility of Blood Transfusion refrigerated storage.
* Reagents are stored in specific refrigerators, cupboards, or shelving depending on required storage conditions. Temperatures are controlled, monitored, and recorded as necessary.
* Storage of waste material for disposal is as described:

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| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Waste Management Procedure** | **LM-SOP-WASTE MAN** |
| **Local Rules** | **LM-POL-LOCAL** |

### 5.2.4 Staff Facilities

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

* Toilet facilities, (♂ & ♀) are available for staff on all three floors of York Pathology. Staff toilets are available on the 1st floor of Scarborough Pathology.
* A rest area is available for use on the 1st floor at both York and Scarborough sites. All rest rooms contain a means of boiling water, a drinking water supply, a refrigerator, a toaster, and a microwave oven.
* Lockers are provided for the storage of outdoor clothes and personal effects.
* Male and female changing areas are provided on the 1st floor at both York and Scarborough sites.
* Coat hooks are provided for hanging up white coats in, or just outside, the rooms in which they are required.
* There is a designated area for the storage of clean laboratory coats.
* Personal protective equipment is provided as necessary to the requirements of the procedures being conducted. Information on this is given in specific SOP for each procedure.

### 5.2.5 Patient Sample Collection Facilities

At York and Scarborough sites phlebotomy is no longer managed by Pathology the function is now being held by Specialist Medicine. Pathology is working with the phlebotomy team to ensure continued compliance with the international standard by providing a checklist for completion when considering the provision of patient sample collection facilities [LM-TEM-SAMPLE COL]. This checklist is subsequently used as an annual check scheduled and retained in the audit module of Q-Pulse under the Health and Safety audit calendar.

The phlebotomy services for York are located on the ground floor in the outpatient department of the hospital and at the Community Stadium on the Vanguard Retail Park. The phlebotomy service for Scarborough is located on the Scarborough hospital site. Full patient access to Phlebotomy includes disabled access and toilet access. The waiting area is separate from the phlebotomy room where samples are procured. Within the phlebotomy room each phlebotomy station is segregated off so that patients are afforded suitable privacy.

The phlebotomy areas have and maintain appropriate first aid materials for both patient and staff need. The sample collection facility used for blood samples (Sarstedt-Monovette) has been selected due to its superior sample collection performance, high level of patient comfort during the procedure and its lack of adverse effect on the quality of result produced following testing.

**Andrology infertility patients at the York site only:**

When necessary, patients may attend to produce a semen sample on site using a specific facility. This is available ONLY by prior booking through a bespoke section of the Laboratory Medicine Website ([www.york.nhs.uk/andrology](http://www.york.nhs.uk/andrology)).

Patients report to the Laboratory Medicine sample reception and will be taken by Cytology staff to the facilities, a short distance from sample reception. The facility provides a quiet and private area for sample production behind a locked door. After production, patients are instructed to let Cytology staff know and Cytology staff will carry out a hygiene and disinfection check of the facilities. The patient sample collection facilities are reviewed as part of the departmental quarterly Health and Safety check.

### 5.2.6 Facility Maintenance and Environmental Conditions

The facilities provided are managed and maintained by YSTHFT Estates & Facilities (LLP). Staff are always required to maintain good housekeeping throughout the laboratory. 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.

The YSTHFT Health and Safety Manager performs an annual inspection of the laboratory facilities on both the York & Scarborough sites in conjunction with the laboratory Health & Safety lead and Quality Manager. The inspection is recorded in the Q-Pulse audit module and any non-conformity or deficiencies found are recorded in the audit module of Q-Pulse, which automatically feeds through to the CAPA module for departmental action and follow up.

Regular discipline specific health and safety inspections check for evidence of clean, uncluttered, well maintained work areas and good housekeeping. Records of inspection reports and actions are stored in the audit module of Q-Pulse which automatically feeds through to the CAPA module for departmental action and follow up.

Separation of incompatible activities is achieved using cabinets and the designated category 3 room in the Microbiology department.

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

## 5.3 Laboratory Equipment, Reagents, and Consumables

### 5.3.1 Equipment

#### 5.3.1.1 General

For the purposes of ISO 15189, laboratory equipment includes hardware and software of instruments, and laboratory information systems.

The laboratory has documented procedures for the selection, purchasing and management of equipment.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy for Equipment Handling** | **LM-POL-EQUIPMENT** |
| **Disposal of Equipment** | **LM-SOP-EQUIPDIS** |



[See 4.6](#page28) for information concerning the selection and purchasing of external services, equipment, reagents, and consumables.

The adequacy and appropriateness of equipment is under constant review by departmental heads in conjunction with senior BMS staff and discussed within discipline specific meetings. With regard to POCT equipment, this is assessed by the POCT co-ordinator for YSTHFT, in conjunction with the POCT committee. Only equipment fit for its intended purpose is used by the laboratory including equipment used for point of care testing.

Laboratory Management aims to ensure that the necessary resources are available through capital and material budgetary submissions. The laboratory submits periodic requests for equipment replacement to the Trust Executive Board to ensure that systems are kept up to date and prior to service quality being impaired due to poor performance. Increasingly the laboratory is obtaining major equipment as part of a Managed Service Contract (MSC) – as part of this there is a commitment from the supplier to provide on-going software and hardware safety enhancements and to discuss technology upgrades / refreshment.

The laboratory maintains a full inventory of equipment within the Asset module of Q-Pulse which informs the owner when replacement is anticipated. The full functionality of the Asset module is in use facilitating the fulfilment of this sub clause of ISO 15189.

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| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **The Equipment Module In Q-Pulse** | **LM-SOP-QP-EQUIPMT** |

#### 5.3.1.2 Equipment Acceptance Testing

Upon installation and prior to use the laboratory verifies equipment to ensure that it is achieving the required performance and that it complies with the requirements relevant to any examinations concerned (see also 5.5.1) in accordance with laboratory policy and guidelines. Before new electrical equipment is put into routine use it is suitably electrically safety tested as per Trust requirements.

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| **Document References** | **Q-Pulse Reference** |
| **Policy and Guidelines for Change Control & Validation (Equipment/ Materials/IT/Staff)** | **LM-POL-VALIDATE** |
| **Laboratory Medicine Equipment Acceptance Template** | **LM-TEM-EQUIP ACCEPT** |

The records of equipment verification are retained within Q-Pulse and should be included in the references within the departmental SOP utilising the specific piece of equipment or the asset itself.

Individual equipment is uniquely labelled with the supplier’s serial number so that each item can be definitively identified within the Q-Pulse Asset Module.

#### 5.3.1.3 Equipment Instructions for use

After installation, full operator training is carried out either on site, at the instrument manufacturer’s premises or at another laboratory. Further training on equipment is designed on an instrument-by-instrument basis by the individual or team commissioning the instrument. Training and competence are recorded in the training module of Q-Pulse as performed and achieved. Physical and logical security ensures that equipment is only used by authorised personnel.

Reference to or inclusion of the manufacturer’s operation manuals are held within the Q-Pulse Document Module to enable accessibility to all staff. The Manufacturer’s instructions are often incorporated into the relevant SOP or quick reference guide for ease of use by staff within the work area ensuring full document control. The equipment must be used as the manufacturer intended. Any deviations from manufacturer’s instructions must be validated and verified.

Programmes for preventive maintenance and monitoring of function are detailed in the SOPs relating to each specific piece of equipment. These SOPs are written by staff members who have been given training by the supplier of the equipment or, where simpler items of equipment are concerned, after reference to the operator manual. As appropriate, monitoring considers specific guidelines such as those of MHRA where utilities of Blood Transfusion are concerned.

#### 5.3.1.4 Equipment Calibration and Metrological Traceability

Procedures for calibration of equipment that directly or indirectly affects examination results are detailed in the individual SOP for each piece of equipment or process and records are kept as stated in these SOPs.

These procedures have been designed to ensure that the criteria of ISO 15189 are met:

1. The conditions of use and the manufacturer’s instructions are taken into account [(see](#page48) [5.3.1.3)](#page48).
2. A record of the metrological traceability of the calibration standard and the traceable calibration of the equipment is maintained.
3. Verification of the required measurement accuracy and the functioning of the measuring at defined intervals.
4. Recording the calibration status and date of calibration.
5. Ensuring that, where correction factors are applied because of calibration, any previous calibration factors are suitably updated.
6. Ensuring that staff are aware that subsequent tampering or adjustment may invalidate any examination results achieved.

Metrological traceability shall be to a reference material or reference procedure of the higher metrological order. Preferably by manufacturers or maintenance companies who are themselves able to prove competence to calibrate the equipment, by holding certification against ISO 17025. Such documentation is acceptable if the manufacturer’s examination system and calibration procedures are used without modification.

Where this is not possible or relevant, then other means for providing confidence in the results will be applied, for example:

* The use of certified reference materials.
* Examination or calibration by another procedure.
* Mutual consent standards or methods which are clearly established, specified, characterised, and mutually agreed upon by all parties concerned.

#### 5.3.1.5 Equipment Maintenance and Repair

All new instruments come with a minimum of one year’s parts and labour warranty. After this initial period, a service contract for preventive maintenance is set up. Visits are scheduled and recorded in the Q-Pulse Asset module to ensure that equipment is maintained in a safe working order. In addition, electrical safety and emergency stop devices are scheduled to be checked and recorded if not included as part of the contracted maintenance.

Procedural SOPs each contain COSHH information and any other necessary risk and risk management information to ensure the safe handling and disposal of any chemicals, radioactive and biological materials by staff authorised to carry out the procedure.

Any item of equipment that suffers damage or that is shown by calibration or otherwise to be defective and unfit for use shall immediately be withdrawn from service and labelled accordingly. The appropriate downtime error sheet shall be completed to record the issue. Alternative arrangements shall be made until the item has been repaired and shown by verification to meet specified acceptance criteria as defined by departmental procedures.

|  |  |
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| **Document References** | **Q-Pulse Reference** |
| **Blood Transfusion Equipment Downtime Error Log** | **BT-TEM-DOWNTIME LOG** |
| **Equipment Error Log Sheet** | **LM-TEM-EQUIP ERR** |
| **Laboratory Medicine Equipment Acceptance Template** | **LM-TEM-EQUIP ACCEPT** |

All such actions are recorded in the Asset module of Q-Pulse to enable prior performance to be assessed and immediate or corrective action taken including the effect on previous examinations and informing users [(see 4.10).](#page30)

The laboratory ensures that reasonable measures are taken to decontaminate equipment before service, repair, or decommissioning. A declaration of contamination status form must be completed prior to an engineer commencing work on any equipment and included for record with the asset record. Procedures for decontamination are detailed in the individual SOP for each piece of equipment or in departmental documents:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Declaration of Contamination Status Form** | **LM-TEM-DECONFORM** |
| **Disinfection and Spillages - Clinical Biochemistry** | **CB-SOP-DISINFECT** |
| **General disinfection and disposal of waste** | **CY-SOP-WASTE** |
| **Disinfection Procedures - Haematology** | **HA-SOP-DISINFECT** |
| **Histopathology Disinfection Procedure** | **HI-SOP-DISINFECT** |
| **Preparation and Guidelines for Use of Disinfectants** | **MB-SOP-H&S-DIS** |

#### 5.3.1.6 Equipment Adverse Incident Reporting

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

|  |  |
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| **Document References** | **Q-Pulse Reference** |
| **SHYPS Policy for Continual Improvement** | **SHY-POL-QUAL IMP** |
| **MHRA Incident Reporting (Equipment)** | **LM-SOP-MHRAREPRT** |
| **Guide to RIDDOR Reporting.** | **LM-INF-RIDDOR** |

#### 5.3.1.7 Equipment Records

Pathology uses the full functionality of the Q-Pulse Asset module to assist in the maintenance of records for each piece of equipment. Records are maintained against the inventory to conform to ISO 15189 to include the following depending on the individual asset and its contribution to the performance of examinations. Where indicated (\*) information is currently maintained in relevant departmental procedures:

1. The identity/type of the equipment.
2. The manufacturer’s name, model and serial number or another unique identifier.
3. Contact information for the supplier or the manufacturer\*.
4. Date of receiving and date of entering service.
5. Current location by room number within the Trust.
6. Condition when received (e.g., new, used, or reconditioned).
7. A link to manufacturer’s instructions\*.
8. A reference to the record that confirmed the equipment’s initial acceptability for use when the equipment is incorporated in the laboratory\*.
9. Maintenance carried out and the schedule for preventive maintenance.
10. A reference to the equipment performance records that confirm the equipment’s on-going acceptability for use. This includes copies of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria, and the due date of the next calibration and or verification to fulfil part or this entire requirement. \*
11. Damage to, or malfunction, modification, or repair of the equipment.

These records are readily available for the lifespan of the equipment or longer as specified in the laboratory’s policy for the retention, storage, and disposal of records [LM-POL-RSDR].

### 5.3.2 Reagents and Consumables

#### 5.3.2.1 General

For the purposes of ISO 15189, reagents include reference materials, calibrators and quality control materials; consumables include culture media, pipette tips, glass slides etc.

Discipline specific procedures are in place within the laboratory for the reception, storage, acceptance testing and inventory management of reagents and consumables guided by the laboratory policy in order to conform to the tertiary sub clauses of ISO 15189.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy: Reception, Storage, Acceptance Testing and Inventory Management of Reagents and Consumables** | **LM-POL-RECEIPT** |
| **Clinical Biochemistry: Reception, Storage, Acceptance Testing and Inventory Management of Reagents and Consumables** | **CB-SOP-RECEIPT** |
| **Haematology: Reception, Storage, Acceptance Testing and Inventory Management of Reagents and Consumables** | **HA-SOP-RECEIPT** |
| **Blood Transfusion: Reagent Diary** | **YBT-SOP-READIARY** |
| **Microbiology: Media, Receipting and the Inventory Management System** | **MB-SOP-MEDIA AND IMS** |
| **Histology: Reception, Storage and Inventory Management of Reagents and Consumables** | **HI-SOP-RECEIPT** |
| **Specific information on acceptance testing can also be in departmental documentation** | **HI-POL-IHC VERIFICATION**  **HI-POL-SS VERIFICATION** |
| **Cytology: Management of Materials** | **CY-SOP-MANMAT** |

#### 5.3.2.2 Reagents and Consumables – Reception and Storage

On the York laboratory site goods are received in the Trust Stores area. Risk assessment has been undertaken which considers a variety of approaches to ensure that the area has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage and deterioration and implemented procedures where required. POCT also have goods delivered to the Pharmacy stores.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **York Stores Risk Assessment** | **LM-HSR-YORK STORE** |

Reagents and consumables are stored according to manufactures’ descriptions and the details of batch numbers (where present) are recorded.

#### 5.3.2.3 Reagents and Consumables – Acceptance testing

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

#### 5.3.2.4 Reagents and Consumables – Inventory Management

Each laboratory department utilises its own system of inventory control for reagents and consumables. Any uninspected or unacceptable items are kept separately from those that have been deemed acceptable for use within the constraints of space.

#### 5.3.2.5 Reagents and Consumable – Instructions for use

A reference to the location of the manufacturer’s instructions for use is recorded in the procedural SOP. The Manufacturer’s instructions are incorporated into the relevant SOP for ease of use by staff within the work area which includes full risk assessment ensuring document control. Any deviations from manufacturer’s instructions must be validated and verified.

#### 5.3.2.6 Reagents and Consumables – Adverse Incident Reporting

Adverse incidents and accidents that can be directly attributed to specific reagents or consumables are recorded as nonconformities within the CAPA Module of Q-Pulse for action and follow up. In addition, any incidents which have resulted in the generation of incorrect results will also be logged via the Trust Datix adverse event reporting system. A serious incident will be alerted to the supplier and to MHRA or HSE if necessary. Any incident where staff harm occurs must also reported in DATIX, depending on the severity of the incident this will be RIDDOR reported by the YSTHFT Health and Safety Management.

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| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **SHYPS Policy for Continual Improvement** | **SHY-POL-QUAL IMP** |
| **MHRA Incident Reporting (Equipment)** | **LM-SOP-MHRAREPRT** |
| **Guide To RIDDOR Reporting.** | **LM-INF-RIDDOR** |

#### 5.3.2.7 Reagents and Consumables – Records

Records of reagents and consumables that contribute to the performance of examinations are kept within the individual laboratory departments as detailed in departmental procedures and determined by the laboratory retention, storage, and disposal of records policy [LM-POL-RSDR]. These records include the following to conform to ISO 15189:

1. Name of the reagent or consumable.
2. Manufacturer’s name and batch code or lot number.
3. Contact details for the item supplier or manufacturer.
4. Date of receipt, expiry (if applicable), first use and where applicable the date the material was taken out of service.
5. Condition when received (e.g., acceptable, or damaged).
6. Manufacturer’s instructions (if applicable).
7. Records of confirmation of acceptance for use.
8. Records that confirm the reagents or consumables on-going acceptance for use.
9. For in-house preparations – details of the person undertaking the preparation and the date of preparation.

## 5.4 Pre-examination processes

### 5.4.1 General

The laboratories have produced comprehensive information for its patients and service users to ensure validity of the results of examinations which is available through the official York Trust website [(See General Information 1.4 Information for Users).](#page11) The policy, Laboratory Medicine Website Access, and Amendments [LM-POL-WEB SITE] provides information on the website and how information is controlled.

### 5.4.2 Information for Patients and Users

As a minimum, this information includes:

1. Location of the laboratory.
2. Types of clinical service provided, including the examinations referred to other laboratories.
3. The laboratory opening hours.
4. Range of examinations offered by the laboratory. This includes:
   * Sample requirements.
   * Primary sample volumes.
   * Any special precautions.
   * Result turnaround times.
   * Biological reference intervals.
   * Clinical decision values.
5. Instructions for completion of request forms.
6. Instructions for preparation of the patient.
7. Instructions for patient collected samples.
8. Instructions for sample transportation, including any special handling needs.
9. Any requirements for patient consent (if required).
10. Criteria for the acceptance and rejection of samples.
11. Factors known to significantly affect the performance of the examination or the interpretation of the results.
12. Availability of clinical advice on ordering examinations and on the interpretation of results.
13. Laboratory’s policy on the protection of personal information (Trust Information Governance

Policy) Laboratory’s complaint procedure (Trust complaints procedure).

Technical and clinical information is available by telephone through the general offices and clinical staff respectively.

Information for patients is provided through the Trust web site via [www.labtestsonline.org.uk.](http://www.labtestsonline.org.uk/)

Further information is supplied as appropriate using a format suitable for NHS patient leaflets to ensure readability. These leaflets are available for patients to download on the Laboratory Medicine Website.

### 5.4.3 Request Form Information

GP surgeries are actively encouraged to request laboratory investigations using the ICE Order Communications Module. Ward Order Communications is available through CPD within the York and Scarborough Hospital sites. Electronic requests have all the required data formatted as mandatory fields and the requestor is prevented from completing the request until all these fields are entered. It has also been found to be the method of choice by our users.

Alternatively, conventional request forms are available for users which are designed to provide all relevant information required to provide a safe and meaningful report including clinical advice and to satisfy internal audit requirements.

The laboratory’s request form or electronic equivalent requires the space for the inclusion of the following information:

1. Patient identification: This includes patient name, gender, date of birth, patient location details, unique identifier (e.g., ideally the NHS number)
2. Requestor identification: This includes name or unique identifier of the requesting clinician, healthcare provider or other person legally authorised to request examinations or use medical information, destination for the report and contact details.
3. Type of primary sample and anatomic site of origin, where relevant (e.g., within histopathology).
4. Examinations requested.
5. Clinically relevant patient information (e.g., patient’s family history, travel and exposure history, communicable diseases).
6. Date and (where relevant) time of primary sample collection.
7. Date and time of sample receipt.

The YSTHFT policy available for all staff for filling in request forms and labelling samples was written by Pathology and clearly states ‘each request to Laboratory Medicine is comprised of two components, the request form and the sample(s). It is essential that both can be accurately linked to the patient concerned and to each other’.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy for Filling in Request Forms & Labelling Samples** | **LM-POL-LABELLING** |

Requests can be made to Pathology verbally, for example urgent tests and add on requests, these must always be confirmed by a request form or electronic equivalent within a given time departmental procedures are available as follows:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Clinical Biochemistry: Add on Tests** | **CB-SOP-ADD ON TESTS** |
| **Adding on Tests in Haematology & Immunology** | **HA-SOP-ADD ON TESTS** |
| **Requests to add on microbiology tests to samples already received** | **MB-SOP-ADD ON TESTS** |

Please note: Verbal Requests are not accepted by the Histology and Cytology Departments as add on tests are not performed.

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

### 5.4.4 Primary Sample Collection and Handling

#### 5.4.4.1 General

Pathology has produced comprehensive information for the proper collection and handling of primary samples to ensure validity of the results of examinations which is available through the official YSTHFT website [(See General Information 1.4 Information for Users).](#page11)

Please note Pathology does not manage the phlebotomy service it is managed by the Medical Specialties.

#### 5.4.4.2 Instructions for Pre-collection Activities

The information includes instructions for pre-collection and collection activities which include:

1. The confirmation of the identity of the patient from whom the sample is to be collected.
2. The verification that the patient meets pre-examination requirements (e.g. fasting status, medication status).
3. in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions or special timing of collection (where required) shall be determined and communicated to the appropriate clinical staff.
4. Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives.
5. Instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected. Completion of the request form or electronic request including the Trust policy for filling in request forms and labelling samples [LM-POL-LABELLING].
6. Recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording the collection time.
7. Instructions for the proper storage conditions before collected samples are delivered to the laboratory.
8. Safe disposal of material used in collection.

Where the user requires deviations from the documented procedure these shall be recorded as a report comment and the information included in all documents containing examination results and communicated to the appropriate personnel.

Documentation is available in Q-Pulse as referenced below:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy for Filling in Forms & Labelling Samples** | **LM-POL-LABELLING** |
| **Phlebotomy / Venepuncture** | **LM-SOP-PHL-VENE** |

#### 5.4.4.3 Instructions for Collection Activities

[See 5.4.4.2](#page55) Instructions for pre-collection activities.

### 5.4.5 Sample Transportation

Pathology provides instructions for post–collection activities which include the packaging of samples for transportation which is available through the official YSTHFT website and Staff Room [(See General Information 1.4 Information for Users).](#page11) The procedures are in in compliance with UN 3373 regulatory requirements.

Please note Pathology does not manage the transport of specimens which is managed by the Trust Estates and Facilities Transport Department.

Documentation is available in Q-Pulse as referenced below:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Transportation & Posting of Specimens** | **LM-SOP-TRANSPORT** |

Each discipline has a procedure for monitoring the transportation of samples to ensure they are transported:

* Within and appropriate time frame appropriate to the nature of the requested examinations
* Within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples
* In a manner that ensures the integrity of the sample and the safety for the carrier, the public and the receiving laboratory in compliance with the established requirements

If the department receives a sample whose integrity is compromised or which could have jeopardized the safety of the carrier, the general public and the receiving laboratory, the sender should be contacted and informed immediately about the measures to be taken to eliminate recurrence and recorded through the DATIX system and Q-Pulse CAPA module.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Blood Sciences Specimen Reception: Monitoring the Transportation of Samples** | **SR-SOP-TRANSPORT** |
| **Monitoring the Transportation of Microbiology Samples** | **SMB-SOP-TRANSPORT** |
| **Cytology: Monitoring the Transportation of Samples** | **CY-SOP-TRANSPORT** |
| **Histology: Monitoring the Transportation of Samples** | **HI-SOP-TRANSPORT** |

### 5.4.6 Sample Reception

York Pathology has five sample reception areas. The first is on the ground floor and is the point of contact between the public and the laboratory. It distributes incoming samples to the relevant disciplines and sends out request forms, blood collection consumables, etc., to surgeries as requested. It also takes receipt of samples from patients who have brought them in personally and hands out collection bottles (e.g., for 24h urine) to patients who have been sent up from outpatients to collect them. The departments of Biochemistry and Haematology share a joint specimen reception area on the 2nd floor of the Pathology block, Non-Gynae Cytology, Histology, and Microbiology all have their own reception areas.

Scarborough Pathology has several reception areas. The Pathology Office is staffed by clerical staff and is the point of contact between the public, surgeries, and the laboratory. The office coordinates supply to the surgeries through the Scarborough Pathology Store man. Specimens are delivered and signed into the specimen receipt room by the Transport staff. On delivering samples a bell is rung to notify the individual departments of delivery. MLAs from the respective departments will then sort the samples and take them to the respective departments. There is also a delivery point where patients can drop off samples which is checked regularly by MLA staff. The departments of Biochemistry and Haematology share a joint specimen reception area on the ground floor; this reception also receives the Cellular pathology and Microbiology samples for transfer to York.

Each department’s procedures for sample reception ensure the following conditions are met.

1. Samples are unequivocally traceable, by request and labelling to an identified patient or site. With the exceptions of Histology and Non-Gynae Cytology, the disciplines supply combination request form/specimen bags to aid in the correct matching of samples to forms. Bar codes or individual laboratory numbers are used for labelling request forms and specimens. All specimens, accompanying request forms and supporting documentation are uniquely identified throughout all stages of investigation by means of the unique laboratory number. All portions of the primary sample are therefore unequivocally traceable to the original primary sample.
2. Laboratory developed criteria for acceptance or rejection of samples are applied.
3. Where there are problems with patient or sample identification, sample stability due to delay in transport or inappropriate container, insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory choses to process the sample, coded comments are added so the final report indicate the nature of the problem and where applicable, that caution is required when interpreting the results.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Biochemistry/Haematology: Sample Labelling & Checking Procedures** | **SR-SOP-RECEPTION** |
| **Blood Transfusion: Samples & Requests** | **BT-SOP-SAMPLES** |
| **Cytology: Receipt and numbering of non- gynaecological specimens** | **CY-SOP-NG REC** |
| **Histology: Reception and Unpacking of Specimens**  **Packaging up Histology and Non-Gynaecological Cytology Specimens to be sent to York** | **HI-SOP-RECEPTION**  **SSR-SOP-HISTO** |
| **Microbiology: Specimen Processing Reception Bench** | **MB-SOP-REC-SORT** |

1. All departments record the request form and specimen details of all samples received electronically using the Telepath system. The date and the time of the receipt and/or the registration of samples is recorded on data entry. The identity of the person registering the request into Telepath is recorded as receiving the sample. All request forms, (including electronic requests) are scanned to permit storage of digital images of the originals.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Biochemistry/Haematology: Request Entry on Telepath** | **SR-SOP-REQENTRY** |
| **Blood Transfusion: Samples & Requests** | **BT-SOP-SAMPLES** |
| **Cytology: Non-Gynaecological Cytology Entry** | **CY-SOP-NGENT** |
| **Histology: Request Entry on Telepath** | **HI-SOP-RECEPTION** |
| **Microbiology: Request Entry on Telepath** | **MB-SOP-TP-ENTRY** |



1. All MLA and BMS staff recorded as competent in specimen reception SOPs are authorised to systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them as detailed in the SOPs. Where there may be doubt about a sample, reception staff consult a relevant member of the laboratory clinical staff [(see 5.1.6 Competency Assessment).](#page41)
2. Procedures, where relevant, are in place for the receipt, labelling, processing, and reporting of samples specifically marked as urgent. These procedures include details of any special handling of the request form and sample, the mechanism of transfer of the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Biochemistry/Haematology: Dealing with Urgent Samples** | **SR-SOP-RECEPTION** |
| **Blood Transfusion: Samples & Requests** | **BT-SOP-SAMPLES** |
| **Cytology: Handling of Urgent FNA's** | **CY-SOP-URGFNA** |
| **Histology: Dealing with Urgent Samples** | **HI-SOP-RECEPTION** |
| **York Microbiology: Specimen Processing Reception Bench** | **MB-SOP-REC-SORT** |

### 5.4.7 Pre-examination Handling, Preparation and Storage

All samples received are stored within the laboratory in compliance with the Laboratory policy for the retention, storage, and disposal of laboratory samples. Departmental 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.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Policy for the retention, Storage and Disposal of Laboratory Samples.** | **LM-POL-RSDS** |

Time limits for requesting additional or further examinations on already received samples are contained within individual SOPs and also provided to users via the official York Trust website [(See](#page11) [General Information 1.4 Information for Users).](#page11)

## 5.5 Examination procedures

### 5.5.1 Selection, Verification and Validation of Examination Procedures

#### 5.5.1.1 General

The laboratory only uses examination procedures which have been validated for their intended use (i.e. Category 1: see Figure 5 below). The performance specifications for each examination procedure relate to the intended use of that examination.

**Category 2:**

A category 1 examination procedure that has been modified or is used outside its intended scope

**Category 3:**

A laboratory developed (in-house) examination procedure

**VERIFICATION** is required before the examination procedure is introduced into routine use of a current document for continuing suitability

**VALIDATION is required before the examination procedure can be classified as a category 1 examination procedure**

**Category 1:**

* A validated examination procedure from a method developer or manufacturer
* Methods published in established / authoritative textbooks, peer-reviewed texts or journals, or nationally or regionally agreed methods

**Figure 5:** Clarification of requirement for Verification and Validation Status within Pathology

The identity of any personnel conducting examination activities is recorded to assist the investigation of nonconformities should they arise, this requirement is met in a number of ways depending on the examination concerned but may include initialling a work list or maintenance schedule or through the audit trail facility on Telepath. It is not currently practicable to include the identity of the verifier in reports.

#### 5.5.1.2 Verification of Examination Procedures

As shown in Figure 5, validated examination procedures are independently verified by Pathology to confirm the performance specification, before being introduced into routine use. The verification is guided by the laboratory policies and procedures as applicable as the performance claims for the examination procedure must be relevant to the intended use of the examination results:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine Policy for Validation and Verification** | **LM-POL-VALIDATE** |
| **Validation and Verification of Examination Procedures** | **LM-SOP-VALIDATE** |

For both verification and validation, the laboratory will keep extensive records of the testing procedures employed, contemporaneous evidence of the results achieved, and evidence of suitable review and acceptance of the data generated. [LM-SOP-VALIDATE] contains a template which must be completed by staff with the appropriate authority within the relevant Pathology department to verify the results of the review.

Historically validation/verification records have been retained within individual departments or stored in the document module of Q-Pulse under evaluations and the relevant department or the appropriate asset record for automated methods. New validations / verifications may now be stored within the Q-Pulse CAPA Module. To avoid confusion records should be referenced within the SOP for the examination procedure.

#### 5.5.1.3 Validation of Examination Procedures

Figure 5, [(see 5.5.1.1 General),](#page59) details which examination procedures Pathology validate. Examination procedures are checked as meeting the needs of users by some or all of the following means as appropriate:

* Making use of journal searches.
* Communicating with suppliers and searching company literature, (Inc. CE marking check).
* Comparing procedures through use of NEQAS and other external audit reports.
* MHRA reports.
* Communication with users whose specialties relate to the specific examination process.
* Benchmarking against HPA national methodology, (Microbiology).

It should be emphasised Pathologies ideal would be a category 1 method.

Laboratory documented procedures applicable for validation are available, the validation is as extensive as is necessary to confirm, through performance characteristics that the specific requirements for the intended use of the examination have been fulfilled and is recorded in Q-Pulse as in Section [5.5.1.2 Verification of Examination Procedures.](#page60) [LM-POL-VALIDATE] also refers to the validation, as appropriate, when changes are required to a validated examination procedure.

#### 5.5.1.4 Measurement Uncertainty of Measured Quality Values

Pathology will determine a measurement of uncertainty value for each examination procedure that produces a measured quantity value. Where examinations include a measurement step but do not report a measured quantity value, the uncertainty of the measurement step is calculated where it has a utility in assessing the reliability of the examination procedure or has influence on the reported result.

These values shall be considered when making interpretations of results. The measurements of uncertainty performance requirements for examinations are defined. Measurement uncertainty values are reviewed at regular defined intervals which aim to minimise the impact of this wherever possible. Measurement Uncertainty values are available to users at the direct request of the user by contacting the department concerned.

Details of measurement uncertainty are contained within individual departmental SOPs which are available via the Documents Module of Q-Pulse:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Clinical Chemistry: Measurement of Uncertainty** | **CB-SOP-UNCERTAINTY** |
| **Haematology: Measurement of Uncertainty** | **HA-SOP-UNCERTAINTY** |
| **Blood Transfusion: Measurement of Uncertainty** | **BT-SOP-UNCERTAINTY** |
| **The Uncertainty of Measurement in Microbiology** | **MB-SOP-UNCERTAINTY** |
| **Factors Affecting Uncertainty of Results** | **HI-POL-UNCERTAINTY** |
| **Measurement of Uncertainty - POCT** | **PC-SOP-UNCERT** |

### 5.5.2 Biological Reference Intervals or Clinical Decision Values

Wherever applicable, biological reference intervals have been calculated for examination procedures and made available to service users via the official York Trust website [(See General](#page11) [Information 1.4 Information for Users).](#page11) The basis for the choice of reference intervals chosen is documented within the SOP.

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

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

When examinations procedures are changed such that results or interpretations are affected *or* *completely new examinations are introduced*, users are notified in advance and reports haveautomatic comments added for a period after introduction as a reminder. Control of change is recorded using the Q-Pulse CAPA module:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **SHYPS Change Control Management Policy** | **SHY-POL-COC** |
| **Managing Nonconformances in the Q-Pulse CAPA Module** | **SHY-SOP-QP-CAPA** |

### 5.5.3 Documentation of Examination Procedures

Each examination procedure within Pathology is documented within an SOP. The SOPs are held within the Document Module of Q-Pulse from which the laboratory or department specific master lists can be obtained. An SOP template [SHY-TEM-SOP] is available via Q-Pulse to guide authors and ensure the SOPs are written in a language and format commonly understood by laboratory staff.

Completing the templates as appropriate fulfils criteria for ISO 15189 which requires in addition to document control identifiers, documentation to include the following as appropriate to the examination procedure:

1. Purpose of the examination.
2. Principle and method of the procedure used for examinations.
3. Performance characteristics (see 5.5.1.2 and 5.5.1.3).
4. Type of sample (e.g., plasma, serum, urine).
5. Patient preparation.
6. Type of container and additives.
7. Required equipment and reagents.
8. Environmental and safety controls.
9. Calibration procedures (metrological traceability).
10. Procedural steps.
11. Quality control procedures.
12. Interferences (e.g., lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions
13. Principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values.
14. Biological reference intervals or clinical decision values.
15. Reportable interval of examination results.
16. Instructions for determining quantitative results when a result is not within the measurement interval.
17. Alert/critical values, where appropriate.
18. Laboratory clinical interpretation.
19. Potential sources of variation.
20. References.

The active copy of an SOP can be viewed by all staff at any Trust networked computer via Q-Pulse. An authorised hard copy is, (or copies are), available for reference at the location(s) of use. As new revisions are produced it is the responsibility of the person stated as having update responsibility in Q-Pulse to destroy these copies and replace them with the new revision.

Records of all copies and their electronic distribution within the laboratory are held on Q-Pulse and the locations of hard copies are also stated on the front page of the SOP. Staffs listed on the electronic distribution are required to electronically acknowledge that they are aware and have read the contents of the document.

Any condensed document formats must correspond to the documented procedure and all documentation must be subject to document control [(See 4.3 Document Control).](#page24)

## 5.6 Ensuring Quality of Examination Results

### 5.6.1 General

Pathology aims to ensure the quality of examinations by performing them under suitably controlled conditions and ensuring appropriate pre-examination and post-examination processes are appropriately implemented. This is ensured by the appropriate use of quality control and participation in external quality assessment schemes.

Quality of results also involves establishing appropriate quality goals, provision of trained staff, operating in suitable premises, suitable environmental conditions and having the requisite equipment, reagents and consumables, including the calibration systems as described within this manual.

This clause in ISO 15189 ends with ‘the laboratory shall not fabricate any results’ – Pathology staffs operate by professional ethical guidelines (See 4.1.1.3 ethical conduct), breaches in ethical conduct of this sort would result in the commencement of disciplinary proceedings.

### 5.6.2 Quality Control

#### 5.6.2.1 General

Each discipline has an internal quality control (IQC) policy which describes procedures designed to verify the attainment of the intended quality of results. Procedures are designed which:

* Define the quality requirements.
* Determine the method precision and bias and set goals for IQC performance.
* Identify prospective IQC performance.
* Predict IQC procedures and select those appropriate

Although the requirements of ISO 15189 regarding IQC are weighted to quantitative examinations there is an equal requirement to monitor performance of other examinations on a regular basis.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Clinical Biochemistry Quality Policy** | **CB-POL-QA** |
| **Microbiology Quality Policy** | **MB-POL-QA** |
| **Haematology Quality Policy** | **HA-POL-QA** |
| **Transfusion Quality Assurance Policy** | **BT-POL-QA** |
| **Histology Quality Policy** | **HI-POL-QUALITY** |
| **Point of Care Quality Policy** | **PC-POL-QA** |

#### 5.6.2.2 Quality Control Materials

The laboratory aims to select, wherever possible, quality control materials that will react in a manner as close as possible to patient samples.

IQC is examined at a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result. The justification for the frequency of examination is included in the departmental SOP.

Wherever possible, concentrations of control materials are chosen at or near clinical decision values to ensure the validity of decisions made and independently sourced third-party QC materials are used to reduce the potential of bias associated with the use of reagents supplied by the system manufacturer.

#### 5.6.2.3 Quality Control Data

Individual laboratory procedures exist to indicate the actions to take to prevent the release of patient results following a failure of QC. Results from patient samples are also evaluated continually after the last successful quality control event which may be by delta check, clinical fit or rolling averages. The process also details the actions to take regarding the re-examination of patient samples following QC rule violations, including the need to assess samples that have been examined since the last successful QC test.

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

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Management of Internal QC within Clinical Biochemistry** | **CB-SOP-IQC** |
| **Management of Internal QC within Haematology** | **HA-SOP-IQC** |
| **Microbiology: Internal Quality Assurance** | **MB-SOP-QC-IQA** |
| **Microbiology: Procedure to Follow in the Event of QC Failure** | **MB-SOP-QCPROCEDURE** |
| **Histology Quality Policy** | **HI-POL-QUALITY** |
| **Management of Internal QC within Cytology** | **CY-SOP-QUALITY** |

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| 5.6.3 Interlaboratory Comparisons |  |  |  |
| 5.6.3.1 Participation |  |  |  |

Each Laboratory discipline has established a documented procedure for the participation in interlaboratory comparison schemes relevant to the testing repertoire undertaken that includes:

* The criteria for the selection of the scheme.
* Defined responsibilities and instructions for participation.
* The monitoring of results and the implementation of corrective action when predetermined performance criteria are not fulfilled.
* Any performance criteria that differ from those of the programme provider.
* The recording of nonconformities to enable discussion with relevant staff and inclusion at the annual management review.
* Full details of the schemes that the laboratory currently participates in.

The laboratory aims to participate in third-party external quality assessment (EQA) schemes relevant to the testing repertoire undertaken. Wherever possible, preference is given to EQA schemes that have been assessed against ISO 17043 or to *International Laboratory Accreditation* *Cooperation* (ILAC) Guidance 13 and have been subsequently accredited by UKAS[(See 4.6](#page28)[External services and supplies).](#page28)

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Clinical Biochemistry: Procedure for the Management of EQA** | **CB-SOP-EQA** |
| **External Quality Assurance Scheme Procedures** | **HA-SOP-EQA** |
| **Transfusion NEQAS Samples** | **BT-SOP-NEQAS** |
| **Microbiology: Investigation of EQA Samples** | **MB-SOP-QC-EQA** |
| **Serology section Quality control & Assurance** | **SE-SOP-QCASSURE** |
| **Histology: Procedure for the Management of EQA** | **HI-SOP-NEQAS** |
| **Cytology: Procedure for the Management of EQA** | **CY-SOP- QUALITY** |
| **POCT: Procedure for the Management of EQA** | **PC-SOP-EQA** |

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#### 5.6.3.2 Alternative Approaches

Where formal inter-laboratory comparison schemes are not available then the laboratory aims to provide objective evidence for the acceptability of examination results via several means, including the use of certified reference material, re-assessment of samples previously examined or exchange of samples with other laboratories.

#### 5.6.3.3 Analysis of Interlaboratory Comparison Samples

The interlaboratory schemes chosen shall as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination, and post examination procedures. To clarify:

* EQA samples are incorporated into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.
* EQA samples are examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.
* The laboratory does not communicate with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data.
* The laboratory does not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

#### 5.6.3.4 Evaluation of Laboratory Performance

Results are monitored and displayed on the laboratory notice board in numerical and graphical format and discussed at departmental staff meetings with relevant staff. All inter-laboratory poor performance is recorded as nonconformities within the CA/PA Module of Q-Pulse together with a description of the preventive actions taken to reduce the possibility of recurrence and the effectiveness of the action taken can be monitored. This information is reported to the monthly laboratory Clinical Governance Meeting and included in the Management Review [(see 4.11 Preventive action),](#page31) [(see 4.15 Management Review).](#page37)

### 5.6.4 Comparability of Examination Results

The laboratory has defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout clinically appropriate intervals. For any type of result, the requirement is to understand the relationship between results obtained in different manners. This is applicable to the same or different procedures, equipment, different sites, or all of these.

Two distinct approaches are used. The first is by the assessment of EQA returns (see 5.6.3 Interlaboratory comparisons) and the second is by the statistical analysis. This is achieved with the use of at least one level of IQC material of the same Lot for each assay that is routinely assayed.

If problems or deficiencies are found, the procedure defines the method of recording the problem or deficiency using the CAPA module of Q-Pulse and, as appropriate, acting on them expeditiously. This shall include notification of users to discuss any implications for clinical practice [(see 4.1.2.6 Communication).](#page21) The specific departmental procedures relating to this clause can be found in the Q-Pulse Document module, please note this clause was considered not applicable within the Cytology and Blood Transfusion departments:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Procedure for ensuring comparability of Biochemistry results** | **CB-SOP-COMPARE** |
| **Procedure for ensuring comparability of Haematology results** | **HA-SOP-COMPARE** |
| **Cross-Site Comparability of Examination Results** | **MB-SOP-COMPARE** |
| **Histology Quality Policy** | **HI-POL-QUALITY** |
| **Histology Proficiency Testing Policy** | **HI-POL-PT** |
| **Advanced tasks for POCT Staff** | **PC-SOP-ADV** |

## 5.7 Post–examination Processes

### 5.7.1 Review of Results

The laboratory has procedures in place to ensure that authorised personnel review the results of examinations before release and evaluate them against internal quality control [(see 5.6.2](#page64) [Quality Control)](#page64) and, as appropriate, available clinical information and previous examination results [(see 4.7 Advisory services).](#page29) Procedures include:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Clinical Biochemistry: Technical Validation Processes** | **CB-SOP-TECHVAL** |
| **Clinical Biochemistry: DEPHO Information Sheet** | **CB-INF-DEPHO** |

All reports undergo a data system check (manual or/and computerised) before issue governed by user defined rules. Any criteria established for automatic selection and reporting of results are reviewed, approved, and documented (See 5.9.1).

### 5.7.2 Storage, Retention and Disposal of Clinical Samples

The laboratory has a documented policy to ensure compliance with this clause. The policy for the retention, Storage and Disposal of Laboratory Samples [LM-POL-RSDS] directs and informs of the relevant procedures for identification, collection, retention, indexing, access, maintenance and safe disposal of clinical samples in accordance with local regulations and recommendations for waste management.

The laboratory aims to comply with the national guidance document ‘*The Retention and Storage* *of Pathological Records and Specimens’* as co-authored by the Royal College of Pathologists(RCPath) and the Institute of Biomedical Science (IBMS).

## 5.8 Reporting of Results

### 5.8.1 General

The documentation of departmental examination procedures [(see 5.5.3)](#page62) provides details of specific reporting requirements for each examination. The laboratory has a defined policy to ensure any result from every examination procedure is reported accurately, clearly, and unambiguously. This policy is also a Trust policy which has been formulated with the views and opinions of users.

Electronic reporting is the method of choice, maximising accessibility and audit trail and reducing the potential for transcription errors. Test results are issued electronically to YSTHFT clinicians (via CPD and ICE) and GPs (via GP link and ICE). Hard copy reports are currently issued only to external hospitals or on specific request. Critical results scoped by departmental SOPs are available by telephone; however, it is not laboratory policy to routinely telephone results.

For examination procedures which involve the transcription of results, for example, reporting of results obtained from reference laboratories or telephone requests the departmental procedure ensures the correctness of the transcription process.

Advice on examinations and interpretation of results is available to meet the needs and requirements of users, firstly by the inclusion of clear, succinct, and unambiguous automatic comments on reports, secondly by the inclusion of comments in the report added manually by the clinical staff and thirdly users can seek further clarification by contacting the clinical staff using the telephone numbers listed on the YSTHFT web site. The laboratory has defined procedures for notifying the requestor when an examination is delayed to the extent it could impact on patient care.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **The Reporting of Laboratory Medicine Results** | **LM-POL-RESULTS** |
| **Notification to users of delays in reporting results from Biochemistry** | **CB-SOP-DELAY** |
| **Haematology: Amending, Delayed and Failed Reports** | **HA-SOP-AMENDRPT** |
| **Microbiology: Procedure for User Notification of Laboratory Delay** | **MB-SOP-TP- REPORT** |
| **Histology: Consultant Reporting Procedure** | **HI-SOP-CON REP** |

### 5.8.2 Report Attributes

Laboratory Management have ensured that the report attributes effectively communicate laboratory results and meets the users’ needs:

1. Comments on sample quality that might compromise examination results are added automatically according to the result and manually after results have been checked by clinical staff.
2. Comments regarding the sample suitability with respect to acceptance/rejection criteria are included to explain any non-reporting of results.
3. Where applicable, critical results, shall be communicated to the user by the aforementioned policy. Electronic and hard copy reports highlight results outside the defined reference range to users by colours, by use of ‘\*’ or comments. Histology and Cytology do not report the sort of numerical data that requires highlighting as abnormal.
4. Interpretive comments on results, where applicable.

### 5.8.3 Report Content

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

1. Identification of the examination, including where appropriate the examination procedure.
2. The identity of the Trust issuing the report, i.e., YSTHFT. The report does not define the laboratory site as the expectation is that users of the service should see no significant difference in the level of service provided on either site irrespective as to whether samples are sent to York or Scarborough for processing.
3. Identification of any tests undertaken by a referral laboratory.
4. Patient identification and patient location on each page of the report.
5. Identification of the requester and the requester’s location.
6. Date of the primary sample and (where appropriate and relevant) the sample collection time.
7. The type of primary sample received.
8. The measurement procedure utilised (if appropriate).
9. Examination results reported in SI units, units traceable to SI units, or other applicable units.
10. Biological reference intervals, clinical decision values (if appropriate).
11. Result interpretation (if appropriate).
12. Cautionary or explanatory notes as discussed in [5.8.2 Report Attributes](#page68).
13. Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available.
14. Identification of the person reviewing the results and authorising the report release. (If this information is not contained on the report, it is readily available from the audit trail on the Laboratory Information Management System).
15. Date of report and time of release (If this information is not contained on the report, it is readily available from the audit trail on the Laboratory Information Management System)
16. Page number to total number of pages (e.g., Page 1 of 5, etc.).

## 5.9 Release of Results

### 5.9.1 General

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

1. Indication in the report if the quality of the primary sample received was unsuitable for examination or could have compromised the quality of the result generated.
2. If an examination result falls within established alert or critical values:
   * Has a physician (or other authorised health professional) been immediately notified?
   * Has a record of this action been made which details – the date & time, the name of the person notified, details of the examination results conveyed, any difficulties encountered in making the notification and the name of the laboratory member who undertook the action?
3. That checks are made to ensure that results are legible, without errors in transcription and that they have been made available only to those authorised to receive them.
4. When results are transmitted as an interim report, the final report is always forwarded to the requestor.
5. If results are distributed via telephone or some other electronic means, then they are only provided to suitably authorised personnel. A record must be kept of all results issued via the telephone (details as shown above) and these must be followed up by the production of a formal written report.

Discipline specific procedures which consider the above and procedures for giving reports by telephone include:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Telephone Reporting and Requesting Procedure** | **BT-SOP-TEL** |
| **Automated Section - Processing Urgent & Phone Requests** | **CB-SOP-TECHVAL** |
| **Giving results by telephone** | **SR-SOP-PHONE** |
| **Telephone Enquires** | **CY-SOP-PHONE** |
| **Urgent Haematology Samples** | **HA-SOP-URGENT** |
| **Telephone Protocol Enquiries and Results Procedure** | **MB-SOP-RES-TEL** |

### 5.9.2 Automated Selection and Reporting of Results

The departments which currently use a system whereby some reports are selected for reporting automatically have specific protocols which cover how this process occurs: The procedures consider:

1. The criteria to be used for automated selection and reporting have been defined and approved by the clinical head of department and are readily available and understood by the staff.
2. The criteria have been fully validated for proper functioning prior to use and are verified following system changes or at periodic intervals to ensure suitable functionality is maintained.
3. The impact that sample interferences (e.g. haemolysis) may have upon the examination results.
4. The process for incorporating analytical warning messages from instruments into the automated selection and reporting criteria.
5. How results selected for automated reporting can be identified at the point of review, in advance of result release and include date and time of selection.
6. How the process can be suspended rapidly if required.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Automated Selection & Reporting of Results** | **CB-POL-AUTO REP** |
| **Reporting of results is detailed within SOPs e.g. FBC Analysis and Authorising describes the process for Full Blood Counts** | **HA-SOP-FBC** |
| **Coagulation Screen SOP includes an overview of auto validation** | **CO-SOP-COAGSCREEN** |
| **Blood Transfusion: Reviewing & Editing Patient Results** | **BT-SOP-EDIT** |
| **Microbiology: Automated Selection & Reporting of Results** | **MB-SOP-TP-REPORT** |

Automated selection and reporting of results do not occur in Cytology, Histology or Immunology. In Blood Transfusion, on the York & Scarborough sites, auto validation only occurs when results match expected patterns any deviations are addressed in BT-SOP-EDIT and REVQ in TPATH preventing release until BMS approval.

### 5.9.3 Revised Reports

In circumstances where it is found necessary to issue a revised report, a new test report is generated in accordance with the Laboratory Medicine – Amending Reported Results SOP available within the Q-Pulse Document Module ensuring the requirements of ISO 15189:2012 are met:

1. The revised report is clearly identified as a revision and includes reference to the date and patient’s identity in the original report.
2. The user is made aware of the revision: If it is necessary to amend a result, a comment is attached to the result indicating that the result has been amended. If a significant anomaly is identified, the user is contacted and notified of the discrepancy.
3. The revised record shows the time and date of the change and the name of the person responsible for the change.
4. The original report entries remain in the record when revisions are made which can be subsequently accessed by those with suitable access rights if required.

In circumstances where the results have been made available for clinical decision making prior to revision, an adverse incident must be recorded using Datix system and subsequently recorded in the Q-Pulse CAPA module with an indication of the action taken to reduce the possibility of a recurrence [(see Risk Management).](#page35)

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Laboratory Medicine – Amending Reported Results** | **LM-SOP-AMENDRES** |
| **Haematology: Amending, Delayed and Failed Reports** | **HA-SOP-AMENDRPT** |
| **Amending Reports in Transfusion** | **BT-SOP-AMENDRPT** |
| **Amending Histopathology Reports** | **HO-SOP-AMNDRPT** |
| **Issuing Microbiology Reports** | **MB-SOP-TP-REPORT** |

## 5.10 Laboratory Information Management

### 5.10.1 General

The laboratory utilises the DXC TP (TELEPATH) system for data management. Telepath acts as a conduit for the flow of data and patient information to and from the laboratory to the user from manual patient request forms and reports, ICE and CPD. The above provides information in line with the needs and requirements of users regarding patient information.

The laboratory ensures controlled access to areas where confidential information may be viewed and ensures controlled access to IT systems where confidential information is stored. Staff are aware of procedures within the laboratory:

* Trust: Security Policy [YT-POL-SECURITY]
* Trust: Data Protection Policy: [YT-POL-DATA PROT]
* Laboratory Medicine Security Policy [LM-POL-SECURITY]

### 5.10.2 Authorities and Responsibilities

The Trust Digital Information Services (DIS) Department provides management of the systems with support of the Laboratory IT Systems Manager within the laboratory Speciality itself.

Generic and discipline specific SOPs are available within the Q-Pulse Document Module which details the authorities and responsibilities of all personnel who use the system and focus in particular on:

1. How to suitably access patient data and information [(5.4.6 Sample Reception)](#page57)
2. Enter patient data and examination results see [(5.4.6 Sample Reception)](#page57)
3. Change patient data or examination results [(see 5.9.3 Revised Reports)](#page71)
4. Authorise the release of examination results and reports [(see 5.9 Release of Results)](#page69)
5. Specific activities relating to the LIMS and its management are undertaken under the direction of the DIS Department and the laboratory IT Systems Manager. Such procedures are documented accordingly in the Q-Pulse Document Module and include:

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Logging 'On' and 'Off' the Computer to Gain Access to Telepath** | **LM-SOP-TP-LOGIN** |
| **Telepath Computer Daily Maintenance** | **LM-SOP-TP-DMAINT** |
| **Telepath Computer Manager Duties** | **LM-SOP-TP-MGR** |
| **Telepath Computer Fault Logging** | **LM-SOP-TP-FAULTS** |

### 5.10.3 Information System Management

The system used for the collection, processing, recording, reporting, storage or retrieval of examination data and information is as previously stated Telepath. The laboratory demonstrates compliance with ISO 15189:2012 a) – g) as follows:

1. Pathology has evidence that the LIMS (i.lab-TP) has been verified as functioning by each department before introduction. Initial verification of the system software was performed and approved for use prior to introduction by the use of formal change control recording and testing. Validation and verification included the proper functioning of interfaces between the LIMS and other systems such as laboratory instrumentation, hospital patient administration systems (CPD) and systems in primary care (ICE). All change control records including all validation data associated with the initial testing (including any contemporaneous screen shot evidence etc.) are retained within the Q-Pulse CAPA Module.

Reports are verified as part of the annual UKAS INTERNAL AUDIT CALENDAR, a screenshot of the softcopy or/and hard copy of the report is obtained and checked to ensure the results and comments are transmitted correctly. The audit template this is included in is AUDIT E (Question 22) and the LIMS VERTICAL AUDIT (Question 26). Please note that some of the historic verification documents are held within the CAPA module, not the document module.

|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Cytology: TELEPATH Verification (Document Module)** | **CY-VERI-LIMS** |
| **Microbiology: TELEPATH Verification – York (Document Module)** | **MB-VERI-TP1307** |
| **Histology: TELEPATH Verification (Document Module)** | **HI-VERI-LIMS** |
| **Blood Transfusion: TELEPATH Verification (CAPA Module)** | **BT-VAL-LIMS** |
| **Blood Transfusion: TELEPATH Verification Prep (CAPA Module)** | **BT-VAL-LIMS PREP** |
| **Haematology and Biochemistry Verification information (CAPA Module)** | **BS-VAL-LIMS** |

1. Documented Pathology and departmental procedures exist for the system which includes day to day functioning of the system [(see 5.10.2 Authorities and Responsibilities).](#page72) These are available within the Q-Pulse Document Module for all authorised staff.
2. Security access to the system is strictly controlled via the Trust DIS security procedures and subsequently via security access control for individual users in compliance with requirements for data protection. Staff are aware that it is a Trust requirement to keep passwords for access to a computer system secret, that they must not write them down anywhere or divulge them to anyone else. The systems prompt changes in Passwords at regular intervals to maintain security. The systems are operated in an environment that complies with supplier specification and are safeguarded against tampering and loss [(see 5.2.2 Laboratory and Office Facilities).](#page44)
3. The Trust has policies in place for Information Governance and allied these to Information Governance Staff Guides which are available to all staff via the Trust intranet site Staff Room. In addition, The laboratory has a defined security policy which reinforces these requirements for laboratory staff [(see 4.1.1.3 Ethical Conduct).](#page14) Staff who have access to computerised personal information relating to patients in the course of their employment must regard such information as strictly confidential. Failure to adhere to these policies and Guides will be regarded as serious misconduct and lead to disciplinary action, which may lead to dismissal.
4. Operational elements are undertaken by the Trust DIS Department who are responsible for the environment they are performed in.
5. System maintenance is undertaken by the Trust DIS Department. Electronic data is also backed up by the Trust’s DIS Department. System failures and the appropriate actions are recorded within the Telepath file record of the Asset Module of Q-Pulse [(see 5.3.1.5 Equipment](#page49) [Maintenance and Repair)](#page49) and with the laboratory IT Systems Manager.
6. Trust policies ensure national requirements regarding data protection are upheld.

Periodic audits shall be carried out to provide an assurance that patient results issued electronically to users are accurately reproduced by the systems external to i.Lab-TP. This is ongoing as new tests are introduced or automated comments are added.

The laboratory has documented contingency procedures to maintain services in the event of failure or downtime in information systems and other scenarios that affect the laboratory’s ability to provide its’ service.

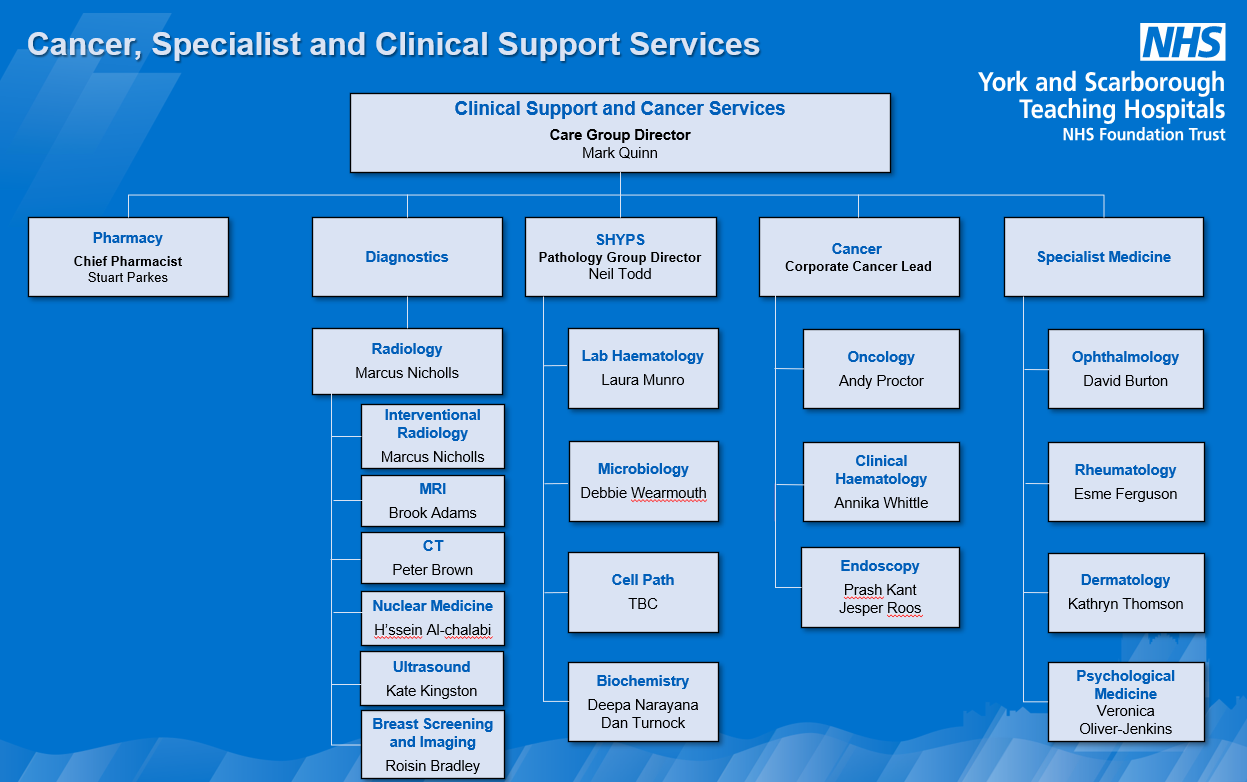
|  |  |
| --- | --- |
| **Document References** | **Q-Pulse Reference** |
| **Telepath Computer Fault Logging** | **LM-SOP-TP-FAULTS** |
| **Microbiology Service Continuity Procedures** | **MB-SOP-CONT PLAN** |
| **Histology Service Continuity Procedures** | **HI-SOP-CONT PLAN** |
| **Clinical Biochemistry Service Continuity** | **CB-SOP-CONT PLAN** |
| **Haematology Service Continuity Procedures** | **HA-SOP-CONT PLAN** |
| **Blood Transfusion Service Continuity Procedures** | **BT-SOP-CONT PLAN** |
| **POCT Service Continuity Procedures** | **PC-SOP-CONT PLAN** |

# Appendix 1: Organisation Charts

## Organisation Chart (1): York & Scarborough Teaching Hospitals NHS Foundation Trust

SHYPS is part of CSCS

## Organisation Chart (2): CSCS Operational Management Team



## Organisation Chart (3): SHYPS Oversight

**YSTHFT**

**Board of Directors**

**YSTHFT Executive Committee**

**HUTH**

**Executive Committee**

**YSTHFT**

**CSCS**

**Governance Pathway:**

**CG Board**

**Quality & Safety Committee**

**CG4 Resources & Performance Committee**

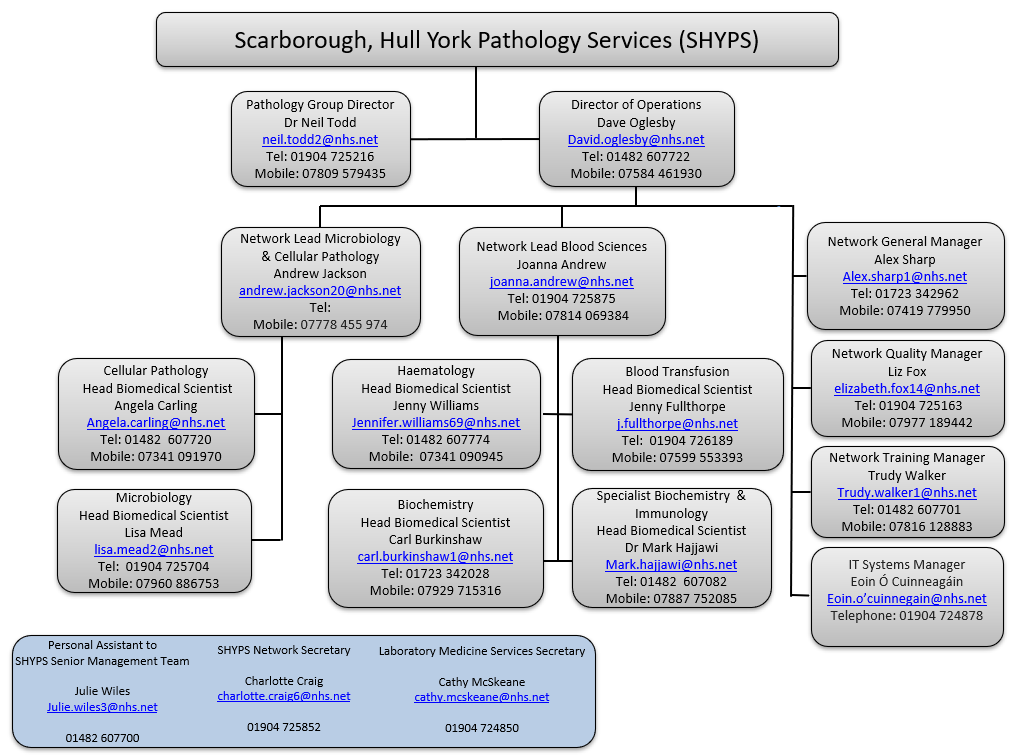
**SHYPS**

**Oversight Committee**

**SHYPS**

**Senior Management Board**

## Organisation Chart (4): SHYPS Senior Management Team Structure



## Organisation Chart (5): York & Scarborough Clinical Biochemistry

Consultant Clinical Scientist:



Clinical Lead

Head Biomedical Scientist:

Carl Burkinshaw

Consultant Clinical Scientist:

Clinical Lead

Dr Dan Turnock

Consultant Clinical Scientist:

Clinical Lead

Dr Dan Turnock

Dr Dan Turnock

Chief Biomedical Scientist:

Emma Lovie

Consultant Clinical Scientist:

Alison Jones

Consultant Chemical Pathologist:

Dr Deepak Chandrajay

Principle Clinical Scientists:

Maria de Ferrars

Claire Lloyd

Senior BMS Staff:

Section Heads & Training Officer

Senior Clinical Scientists:

Naomi Carne

BMS Staff

York

BMS Staff

Scarborough

MLA Staff

(Managed by MLA & Lab Admin Manager in York and the Site Manager in Scarborough)

## Organisation Chart (6): York & Scarborough, Specialist Biochemistry

Consultant Clinical Scientist:

Head Biomedical Scientist:

Dr Mark Hajjawi

Clinical Lead

Consultant Clinical Scientist:

Clinical Lead

Dr Dan Turnock

Consultant Clinical Scientist:

Clinical Lead

Dr Dan Turnock

Dr Dan Turnock

Consultant Clinical Scientist:

Alison Jones

Consultant Chemical Pathologist:

Dr Deepak Chandrajay

Senior BMS Specialist Biochemistry:

Rachel Navin

Principle Clinical Scientists:

Maria de Ferrars

Claire Lloyd

AP for Specialist Biochemistry

Senior Clinical Scientists:

Naomi Carne

Specialist Biochemistry tests and Immunology tests are performed by staff members from the Biochemistry and Haematology teams respectively, with further test being performed by Hull.

Daily operation responsibilities are overseen by the Chief BMS for the York and Scarborough laboratories.

MLA Staff

(Managed by MLA & Lab Admin Manager in York and the Site Manager in Scarborough)

BMS Staff

Rotate into sections from the Biochemistry or Haematology team

## Organisation Chart (7): York & Scarborough Haematology

MLA Staff

(Managed by MLA & Lab Admin Manager in York and the Site Manager in Scarborough)

Head Biomedical Scientist:

Jenny Williams

Chief Biomedical Scientist:

Richard Adams

Senior BMS Staff

York & Scarborough sites

Section Heads & Training Officer

BMS Staff

Scarborough

BMS Staff

York

Senior House Officer

Specialist Registrar

(1yr rotas from Leeds)

Consultant Haematologist:

Vacant post

Consultant Haematologist:

Dr J. Shields

Consultant Haematologist:

Dr M. Naveed

Consultant Haematologist:

Dr A. Bachh

Consultant Haematologist:

Dr K. Foley

Consultant Haematologist

Laboratory Lead:

Dr L. Munro

Consultant Haematologist

Clinical Lead:

Dr A. Whittle

## Organisation Chart (8): York & Scarborough Blood Transfusion

Consultant Haematologist

Laboratory Lead:

Dr L. Munro

Consultant Haematologist

Clinical Lead:

Dr A. Whittle

Head Biomedical Scientist:

Jenny Fullthorpe

Chief Biomedical Scientist:

Gemma Maxwell

Consultant

Haematologist:

Dr A. Bachh

Consultant Haematologist:

Dr K. Foley

Consultant Haematologist:

Dr J. Shields

Consultant Haematologist:

Dr M. Naveed

Blood Transfusion Practitioner:

Grade F Nurse

Catrina Ivel

Senior BMS Staff

York & Scarborough sites

Section Heads & Training Officer

Consultant Haematologist:

Vacant post

BMS Staff

Scarborough

BMS Staff

York

Associate Practitioners

Specialist Registrar

(1yr rotas from Leeds)

MLA Staff

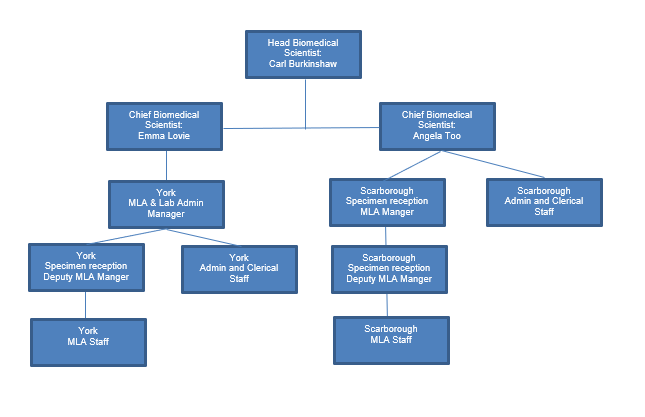
(Managed by MLA & Lab Admin Manager in York and the Site Manager in Scarborough)

Senior House Officer

## Organisation Chart (9): York & Scarborough Blood science specimen reception

 Head Biomedical Scientist:

Carl Burkinshaw



Head Biomedical Scientist:

Carl Burkinshaw

## Organisation Chart (10): York Cellular Pathology

Head Biomedical Scientist:

Angela Carling

Consultant Histopathology Lead Clinician:

Vacant

Consultant Histopathologists:

Dr I. Abdul-Kadir, Dr S. Alderson, Dr M. Al-Kaseem, Dr M. Babawale, Dr C. Bratten, Dr I. Hanson, Dr K Miller, Dr M. Toy, Dr S. Toy

Chief Biomedical Scientist:

Helen Armitage

Senior BMS Staff

Advanced Practitioners

Associate Specialist/Trust Grade Histopathologists

Registrar Histopathologists

BMS Staff

Medical Secretaries & Clerical Officer Managed by Imogen Fairburn

MLA Staff

## Organisation Chart (11): Microbiology York & Scarborough

Consultant Microbiologist:

Clinical Lead

Dr D. Wearmouth

Head Biomedical Scientist:

Lisa Mead

BMS Staff

York

Admin & Clerical

Staff

York

Admin & Clerical

Team Leader

York

MLA Staff

Deputy MLA Manager

MLA Manager

Senior BMS

York

Consultant Microbiologist

Dr D. Hamilton

Consultant Microbiologist: Dr D. Mawer

Network Chief Biomedical Scientist:

Rachel Thompson

Chief Biomedical Scientist:

Natalie Fettes

Senior BMS

York

Specialist Registrar

Associate Practitioners

York

Consultant Clinical Scientist:

Dr B. Neish

Consultant Microbiologist: Dr K. Blackmore

## Organisation Chart (12): POCT

Consultant Chemical Pathologist:

Dr Deepak Chandrajay

Head Biomedical Scientist:

Dr Mark Hajjawi

York & Scarborough Trust

POCT Committee

York & Scarborough Trust

Medical Devices Committee

York& Scarborough Trust

Patient Safety Group

Committee

York & Scarborough

Senior BMS:

Rachel Lampard &

Clemora Wilkinson

Associate Practitioner

Community

Associate Practitioner

Scarborough

BMS

York & Scarborough

Associate Practitioner

Shared Line management responsibility with Scarborough Haematology

(Bridlington)

MLA

York

MLA

Community

POCT Users

Clinical and Nursing Staff, HCA’s OPD’s

## Organisation Chart (13): York & Scarborough Teaching Hospital NHS Foundation Trust: Human Tissue Authority – Roles and Responsibilities

Medical Director:

York & Scarborough Teaching Hospitals NHS Foundation Trust

Chief Executive:

Simon Morritt

**Key**

Line of accountability

Responsibility to

Pathology Group Director: Dr N. Todd

Designated Individual:

Dr D. Oglesby

Bereavement Midwife

Person Designate:

Bev Shelley

York Histology Dept.

Person Designate

Consultant Biomedical Scientist

Helen Love

Mortuary APT

Person Designate (APT3)

Scarborough:

Chris Williams

Bereavement Services

Person Designate Lead Nurse for End of Life Care:

York Emergency Dept.

Person Designate

Consultant Paediatrician

Dr J. Vermeulen

Mortuary Manager

Person Designate (APT3)

York:

Kevin Breheney

## Organisation Chart (14): Antenatal Screening Program: Sickle Cell & Thalassaemia

Deputy Director of Midwifery

York & Scarborough

Sarah Ayre

Matron for Maternity

York & Scarborough

Director of Midwifery

York & Scarborough

Sue Glendenning

Consultant Haematologist

Laboratory Lead:

Dr L. Munro

Head Biomedical Scientist:

Jenny Williams

Chief Biomedical Scientist:

Richard Adams

**Key**

Laboratory Responsibility

Link to Trust Obstetrics

& Gynaecology

Screening Support Midwife

Scarborough

Mrs J. Boyce

Laboratory Technical Lead for Antenatal Screening Service

Kate Vardigans

Deputy Laboratory Technical Lead for Antenatal Screening Service

Stephen Leather

BMS Staff

York & Scarborough

Screening Support Midwife

York

Mrs C. Hodgson

Antenatal Screening Coordinator

York & Scarborough

Ms J. Moreton

## Organisation Chart (15): Antenatal Screening Program: Infectious Diseases in Pregnancy Screening

Sue Glendenning

Head of Midwifery

York & Scarborough

Sue Glendenning

Head Biomedical Scientist:

Lisa Mead

Consultant Microbiologist

Laboratory Clinical Lead:

Dr D. Wearmouth

Deputy Head of Midwifery

York & Scarborough

Sarah Ayre

Chief Biomedical Scientist:

Natalie Fettes

**Key**

Laboratory Responsibility

Link to Trust Obstetrics

& Gynaecology

Matron for Maternity

York & Scarborough

Screening Support Midwife

Scarborough

Mrs J. Boyce

Screening Support Midwife

York

Mrs C. Hodgson

Antenatal Screening Coordinator

York & Scarborough

Ms J. Moreton

Laboratory Technical Lead for Antenatal Screening Service

Caroline Tanner

BMS Staff

York & Scarborough

Deputy Laboratory Technical Lead for Antenatal Screening Service

Rotational BMS team to deputise

# 