

## Laboratory Medicine Quality Manual

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### **Changes from last version of this document**

Amendment to Organisational Chart 6: Cytology - HBPC changed to CSPL and line of accountability of CSPL is directly to Dr James Taylor.

Addition of Organisational Chart 10: Antenatal Screening Programme: Sickle Cell & Thalassaemia

## 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 Directorate of Laboratory Medicine, York Teaching Hospital NHS Foundation Trust.

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.

### A. Use of UKAS logo:

In accordance to 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:

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

<https://www.ukas.com/services/technical-services/how-to-use-the-ukas-symbol/>

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 (QARC) and the Health and Social Care Act (CQC). Cross links to the different standards is presented in appendix 1 of this document.

### B. 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 to 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.

All processes and procedures specified herein are mandatory within the Directorate of Laboratory Medicine.

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

Laboratory Medicine Quality Manager

## Table of Contents

<b>General Information .....</b>	<b>8</b>
1.1 Purpose .....	8
1.2 Laboratory Medicine Service Scope .....	10
1.3 Quality Policy .....	11
1.4 Information on Laboratory Medicine Services .....	11
<b>References.....</b>	<b>11</b>
<b>Definitions .....</b>	<b>11</b>
<b>4.0 Management Requirements .....</b>	<b>13</b>
<b>4.1 Organisation and Management Responsibility .....</b>	<b>13</b>
4.1.1 Organisation .....	13
4.1.1.1 General.....	13
4.1.1.2 Legal Entity .....	13
4.1.1.3 Ethical Conduct .....	14
4.1.1.4 Laboratory Director .....	15
4.1.2. Management Responsibility .....	18
4.1.2.1. Management Commitment .....	18
4.1.2.2. Needs of Users .....	18
4.1.2.3. Quality Policy .....	19
4.1.2.4. Quality Objectives and Planning .....	20
4.1.2.5. Responsibility, authority and interrelationships .....	20
4.1.2.6. Communication .....	21
4.1.2.7. Quality Manager .....	22
<b>4.2 Quality Management System (QMS) .....</b>	<b>22</b>
4.2.1. General requirements .....	22
4.2.2. Documentation requirements .....	23
4.2.2.1 General.....	23
4.2.2.2 Quality Manual .....	24
<b>4.3 Document Control.....</b>	<b>24</b>
<b>4.4 Service Agreements .....</b>	<b>26</b>
4.4.1 Establishment of Service Agreements .....	26
4.4.2 Review of Service Agreements .....	27
<b>4.5 Examination by Referral Laboratories .....</b>	<b>27</b>
4.5.1 Selecting and Evaluating Referral Laboratories and Consultants .....	27
4.5.2 Provision of Examination Results .....	28
<b>4.6 External Services and supplies .....</b>	<b>28</b>
<b>4.7 Advisory Services .....</b>	<b>29</b>

<b>4.8 Resolution of complaints</b>	<b>29</b>
<b>4.9 Identification and Control of Nonconformities</b>	<b>30</b>
<b>4.10 Corrective Action</b>	<b>30</b>
<b>4.11 Preventative Action</b>	<b>31</b>
<b>4.12 Continual Improvement</b>	<b>32</b>
<b>4.13 Control of Records</b>	<b>32</b>
<b>4.14 Evaluation and audits</b>	<b>33</b>
4.14.1 General	33
4.14.2 Periodic Review of Requests, and Suitability of Procedures and Sample Requirements	33
4.14.3 Assessment of User Feedback	34
4.14.4 Staff Suggestions	34
4.14.5 Internal Audit	35
4.14.6 Risk Management	35
4.14.7 Quality Indicators	35
4.14.8 Reviews by External Organisations	36
<b>4.15 Management Review</b>	<b>37</b>
4.15.1 General	37
4.15.2 Review input	37
4.15.3 Review Activities	38
4.15.4 Review Output	38
<b>5.0 Technical Requirements</b>	<b>38</b>
<b>5.1 Personnel</b>	<b>38</b>
5.1.1 General	38
5.1.2 Personnel Qualifications	39
5.1.3 Job Descriptions	39
5.1.4 Personnel Introduction to the Organizational Environment	39
5.1.5 Training	40
5.1.6 Competency Assessment	41
5.1.7 Reviews of Staff Performance	42
5.1.8 Continuing Education and Professional Development	42
5.1.9 Personnel Records	43
<b>5.2 Accommodation and Environmental Conditions</b>	<b>43</b>
5.2.1 General	43
5.2.2 Laboratory and Office Facilities	44

5.2.3 Storage Facilities .....	44
5.2.4 Staff Facilities .....	45
5.2.5 Patient Sample Collection Facilities.....	46
5.2.6 Facility Maintenance and Environmental Conditions .....	47
<b>5.3 Laboratory Equipment, Reagents, and Consumables .....</b>	<b>47</b>
5.3.1 Equipment .....	47
5.3.1.1 General.....	47
5.3.1.2 Equipment Acceptance Testing .....	48
5.3.1.3 Equipment Instructions for use.....	48
5.3.1.4 Equipment Calibration and Metrological Traceability .....	49
5.3.1.5 Equipment Maintenance and Repair.....	49
5.3.1.6 Equipment Adverse Incident Reporting .....	51
5.3.1.7 Equipment Records.....	51
5.3.2 Reagents and Consumables .....	51
5.3.2.1 General.....	51
5.3.2.2 Reagents and Consumables – Reception and Storage .....	53
5.3.2.3 Reagents and Consumables – Acceptance testing .....	53
5.3.2.4 Reagents and Consumables – Inventory Management.....	53
5.3.2.5 Reagents and Consumable – Instructions for use .....	53
5.3.2.6 Reagents and Consumables – Adverse Incident Reporting.....	53
5.3.2.7 Reagents and Consumables – Records .....	54
<b>5.4 Pre-examination processes .....</b>	<b>54</b>
5.4.1 General.....	54
5.4.2 Information for Patients and Users .....	54
5.4.3 Request Form Information .....	55
5.4.4 Primary Sample Collection and Handling.....	56
5.4.4.1 General.....	56
5.4.4.2 Instructions for Pre-collection Activities.....	56
5.4.4.3 Instructions for Collection Activities .....	57
5.4.5 Sample Transportation.....	57
5.4.6 Sample Reception .....	58
5.4.7 Pre-examination Handling, Preparation and Storage.....	60
<b>5.5 Examination procedures .....</b>	<b>60</b>
5.5.1 Selection, Verification and Validation of Examination Procedures.....	60
5.5.1.1 General.....	60
5.5.1.2 Verification of Examination Procedures .....	61
5.5.1.3 Validation of Examination Procedures.....	62
5.5.1.4 Measurement Uncertainty of Measured Quality Values .....	62
5.5.2 Biological Reference Intervals or Clinical Decision Values .....	63
5.5.3 Documentation of Examination Procedures .....	63
<b>5.6 Ensuring Quality of Examination Results .....</b>	<b>64</b>
5.6.1 General.....	64
5.6.2 Quality Control .....	65
5.6.2.1 General.....	65

5.6.2.2 Quality Control Materials .....	65
5.6.2.3 Quality Control Data .....	65
5.6.3 Interlaboratory Comparisons .....	66
5.6.3.1 Participation .....	66
5.6.3.2 Alternative Approaches .....	67
5.6.3.3 Analysis of Interlaboratory Comparison Samples .....	67
5.6.3.4 Evaluation of Laboratory Performance .....	67
5.6.4 Comparability of Examination Results .....	67
<b>5.7 Post-examination Processes .....</b>	<b>68</b>
5.7.1 Review of Results .....	68
5.7.2 Storage, Retention and Disposal of Clinical Samples .....	68
<b>5.8 Reporting of Results .....</b>	<b>68</b>
5.8.1 General .....	68
5.8.2 Report Attributes .....	69
5.8.3 Report Content .....	70
<b>5.9 Release of Results .....</b>	<b>70</b>
5.9.1 General .....	70
5.9.2 Automated Selection and Reporting of Results .....	71
5.9.3 Revised Reports .....	72
<b>5.10 Laboratory Information Management .....</b>	<b>73</b>
5.10.1 General .....	73
5.10.2 Authorities and Responsibilities .....	73
5.10.3 Information System Management .....	74
<b>Appendix 1: Related Standards/sub-clauses and Regulatory Body .....</b>	<b>76</b>
<b>Appendix 2: Organisation Charts .....</b>	<b>82</b>
Organisation Chart (1): York Teaching Hospital NHS Foundation Trust .....	82
Organisation Chart (2): Laboratory Medicine Management Structure for the Integrated Service .....	83
Organisation Chart (3): York & Scarborough Clinical Biochemistry .....	84
Organisation Chart 4: York Haematology, Transfusion & Immunology .....	85
Organisation Chart (5): York & Scarborough Histopathology .....	86
Organisation Chart (6): North Yorkshire Cytology Screening Service .....	87
Organisation Chart (7): Microbiology York & Scarborough .....	88
Organisation Chart (8): POCT .....	89
Organisation Chart (9): York Teaching Hospital NHS Foundation Trust: Human Tissue Authority – Roles and Responsibilities .....	90
Organisation Chart 10: Antenatal Screening Programme: Sickle Cell & Thalassaemia .....	91
<b>Appendix 3: Management Groups, Committees, and Meetings Schedules .....</b>	<b>92</b>



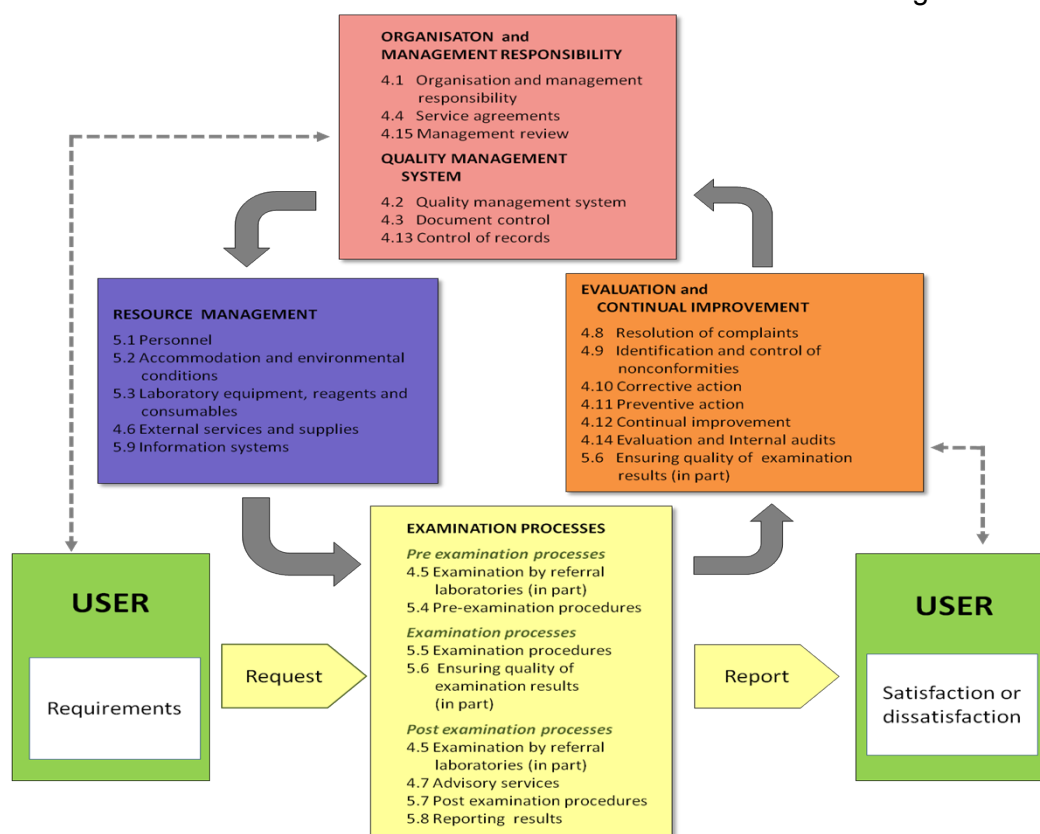
## General Information

### 1.1 Purpose

This Quality Manual describes the Quality Management System (QMS) in use throughout this laboratory for the benefit of the directorate's own management and 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 department'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 Laboratory Medicine, as part of York Teaching Hospital NHS Foundation Trust, seeks to comply with the particular 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 Laboratory Medicine 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**

York Teaching Hospital NHS Foundation Trust was granted foundation status on 1 April 2007. The Trust provides a comprehensive range of acute hospital and specialist healthcare services for



approximately 530,000 people living in and around York, North Yorkshire, North East Yorkshire and Ryedale - an area covering 3,400 square miles.

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 centre of everything we do
- Caring about what we do
- Respecting and valuing each other
- Listening in order to improve
- Always doing what we can to be helpful

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 North East Yorkshire Healthcare NHS Trust, bringing Scarborough and Bridlington Hospitals into the organisation.

Laboratory Medicine is part of, and provides Laboratory services to, York Teaching Hospital NHS Foundation Trust and serves the associated community and primary care providers.

The acquisition of Scarborough and North East Yorkshire NHS Trust in July 2012 meant that the departments of Laboratory Medicine (York) and Pathology (Scarborough) have been required to integrate into a single service.

The UKAS document TPS 51: Accreditation of Multi – Site Laboratories [LM-INF-TPS 51] 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 makes reference to multi-site laboratory accreditations. Laboratory Medicine 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].

Laboratory Medicine aims to deliver a directorate across two sites that share a unified management structure ([Appendix 3 – Laboratory Medicine Management Structure for an Integrated Service](#)) with a single Quality Management System and a single Quality Manual. As far as possible, policies and procedures will apply to both sites. At a departmental level, it is envisaged that there will be identical analysers and processes across the two sites providing compatibility of results across the integrated departments. 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 York Laboratory is: ~**

Laboratory Medicine  
York Teaching Hospital  
Wigginton Road  
York, YO31 8HE

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

Laboratory Medicine  
Scarborough Hospital  
Woodlands Drive,  
Scarborough, YO12 6QL

## **1.2 Laboratory Medicine Service Scope**

### **Clinical Biochemistry**

Clinical Biochemistry provides a 24-hour/365 day high quality analytical service to assist in the rapid diagnosis of disease. Testing undertaken includes routine biochemistry, endocrinology, toxicology and specific protein analysis. A twenty-four hour consultant led advisory service is also in operation. The Clinical Biochemistry department operates on both the York and Scarborough sites.

### **POCT**

POCT operates as a section of Clinical Biochemistry but takes advice from other departments, as appropriate, to provide a comprehensive POCT service. The POCT team provides training and support for users on the York, Scarborough and Bridlington Hospital sites and also satellite units such as Easingwold and the community. The team covers all POCT, ranging from dipsticks to sophisticated analytical instruments.

### **Haematology/Transfusion/Immunology**

The Haematology department, including Blood Transfusion and Immunology, provides a high quality diagnostic service and is committed to achieving and maintaining the highest possible standards, delivering a 24 hour, 7 day per week comprehensive consultative and diagnostic service throughout the Trust and beyond. The Blood Transfusion department provides blood products for use in clinical emergencies and routine procedures. Haematology and Blood Transfusion Departments operate on both the York and Scarborough sites. Immunology is based solely at the York site.

### **Microbiology**

The department of Microbiology offers a high quality, 24-hour interpretative diagnostic Microbiology service to local hospitals and the community. As well as routine bacteriological culture, the department offers serological testing, liquid mycobacterial culture and rapid molecular detection techniques for the diagnosis of chlamydia. The department works in collaboration with the HPA and regional CCDCs to contribute to epidemiological surveillance and public health medicine. The Microbiology department operates on both the York and Scarborough sites.

### **Cytology**

Cytology provides a high quality diagnostic service in both gynaecological and non-gynaecological cytology, (including the Breast Cytology Screening Unit at York), within York Teaching Hospital NHS Foundation Trust and acts as a regional cytology service as part of the NHS Cervical Screening Programme, (NHSCSP).

The North Yorkshire Cervical Cytology Screening Service provides a diagnostic gynaecological screening service including HPV testing to the whole of North Yorkshire, (excepting Craven district), Hull and the East Riding, North Lincolnshire and Goole. The Cytology Department operates from the York site

### **Histology**

Histology aims to provide a high quality diagnostic pathology service to York Teaching Hospital NHS Foundation Trust and the wider community. Investigations undertaken to achieve this include routine histological technique and a wide range of special staining methods, while rapid diagnosis is available through the utilization of frozen section techniques. In Immunocytochemistry, a comprehensive repertoire of antibodies is used to identify tissue antigen sites as an aid to diagnosis, particularly in cancer. The Histology Department operates from the York site and covers both York and Scarborough Hospitals.

### **Mortuary**

The York Teaching Hospital Mortuary provides a high quality mortuary service to patients who die either in hospital or in the community and to their bereaved family and friends on both the York and Scarborough site. Scarborough Hospital is licensed with the Human Tissue Authority as a satellite location under the York Trust license. The Mortuary service ensures respect, dignity and sensitivity in handling the deceased and in playing a vital role in supporting bereaved families whilst also ensuring strict health and safety guidelines are followed. Mortuary staff provide a service involving around 500 post mortems per annum from the hospital and local community as well as providing a coronial service for the York and Selby area. Staff work closely with the Trust Porter staff, Trust Patient and Liaison Services, Funeral Directors, the Coroner and Coroner's Office and the Police Service.

### 1.3 Quality Policy

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

### 1.4 Information on Laboratory Medicine Services

A guide to the Laboratory Medicine service is available to all users through the official York Trust website, A-Z of Services which includes Laboratory Medicine:

#### [York Hospitals Website](#)

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 Document Control](#)). Laboratory Medicine does not produce a hardcopy handbook owing to difficulties in control, cost and updating.

## References

Medical laboratories – Requirements for quality and competence (ISO 15189:2012) – available to purchase from: <http://shop.bsigroup.com/upload/forms/multi-user-licence-request.html>

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

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

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

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

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

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

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

Trust Management Policies and Procedures – available via [Staff Room](#) Trust intranet site.

URL links to Trust documentation have been included in Q-Pulse to maintain corporate document control integrity.

## Definitions

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
CPD – Core Patient Database. The Trust clinical area for requesting and viewing patient records.
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.
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)
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)
Trust - York Teaching Hospital NHS Foundation Trust.
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

## 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 Laboratory medicine is detailed in the [General Information](#) section of the Quality Manual. This Quality Manual [LM-INF-QUALMAN] explains, standard by standard, how this is achieved.

##### 4.1.1.2 Legal Entity

York Teaching Hospital NHS Foundation Trust (the Trust) received its provider license (number 130145) from Monitor in April 2007. The Trust is also registered with the Care Quality Commission (CQC). The Trust is the entity that is held legally responsible for all its activities and, under the terms of the Health and Social Care Act (2012) the Trust is assessed for regulatory compliance against the act by both Monitor and CQC. The NHS Litigation Authority is the administrator of the

Liabilities Third Parties Scheme (LTPS) covering NHS organisations in England and confirms membership of the Trust [LM-REC-INSURE]. Laboratory Medicine is a directorate of the Trust in its own right.

#### 4.1.1.3 Ethical Conduct

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

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

To achieve these requirements, Laboratory Medicine 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: Professional Registration Policy [YT-POL-REGISTRATION]
- Laboratory Medicine will comply with specific arrangements established by the Trust with regards to the following, which support fairness, equality and high standards of business and professional practice. Laboratory Medicine will comply with the Trust 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: Sickness Absence Policy: [YT-POL-SICKNESS]
- 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 Teaching Hospital NHS Foundation Trust has been granted HTA licence (Licence number 12093) in the post mortem sector confirming continuing acceptability for activities.

<https://www.hta.gov.uk/establishments/york-teaching-hospital-nhs-foundation-trust-12093>

- Require and ensure all staff participates in the Trust Statutory Mandatory Training Program. The ethical conduct expected from all staff is outlined at Trust Corporate Induction.

Information Governance training is included as part of the on-going training programme recorded on the Trust Learning Hub entered via Trust Intranet site Staff Room.

- Trust: Information Governance Policy: [YT-POL-INF GOV]
- 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 within Laboratory Medicine:
  - 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 Clinical Director is a member of the executive board of the Trust and is responsible to the medical director. Please see [Organisational Chart \(1\)](#) for York Trust.

The Clinical Director has ultimate accountability for the overall operation and direction of Laboratory Medicine. 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 organisation charts presented in [Appendix 2](#) clearly defines the hierarchy within Laboratory Medicine and its' position with the Trust as a whole. The Clinical Director has clinical responsibility whereas the Directorate Manager has operational responsibility.

Duties and responsibilities of the Clinical Director are devolved to designees as appropriate; however, ultimate responsibility resides with the Clinical Director. The relevant designee is chosen from the Directorate Manager, Departmental Clinical Leads, and Departmental Head BMS as suitable for the responsibility or duty concerned. The duties of the Clinical Director and designees are documented in their job descriptions. The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of ISO 15189:2012. As specified in the standard the Laboratory Director (or designate/s) shall:

- a) Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;

The Directorate Manager has operational responsibility for the directorate and is the prime budget holder for the directorate. Laboratory Medicine has a member of the Trust Finance Team dedicated to it who works closely with the Directorate Manager and Head BMS staff and attends management meetings in Laboratory Medicine.

- b) Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;

Job descriptions of the Directorate Manager, Head BMS and Quality Manager within the Laboratory Medicine management team provide evidence of the documented delegation of this responsibility.

- c) Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;

The Job description of the Directorate Manager provides evidence of the documented delegation of this responsibility. Head BMS & Operational Managers assist in the processes of staff management within their departments, including recruitment, sickness management and performance management.

d) Ensure the implementation of the quality policy;

The Quality Manager is responsible to the Directorate Manager and accountable to the Clinical Director. A principle duty of the Quality Manager is to draw up and maintain the Laboratory's Quality Manual which incorporates the Quality Policy.

e) Implement a safe laboratory environment in compliance with good practice and applicable requirements;

The Deputy Quality Manager & Health and Safety Lead is responsible to the Directorate Manager and accountable to the Clinical Director and leads the Health and Safety agenda for the directorate with particular emphasis and responsibility for the maintenance of a safe working environment for all individuals who have contact with the Directorate. The Health and Safety Lead is IOSH trained.

f) Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;

The Clinical Director for Laboratory Medicine is Dr. Neil Todd, (MB ChB) who is registered with the General Medical Council (GMC) on the specialist register for Medical Microbiology and Virology. Dr. Todd. Each Laboratory Medicine discipline is professionally directed by a clinical lead who is a medical consultant or clinical scientist of equivalent status, and who has membership of the Royal College of Pathologists or equivalent. These individuals are accountable to the Clinical Director.

g) Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;

Each Laboratory Medicine discipline is able to provide clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results from the particular departmental clinical team. These individuals are accountable to their clinical lead and the clinical director. If the departmental speciality is unable to provide appropriate advice a service level agreement will be put in place with a designated individual who has been selected as competent to provide that clinical advice.

- A Service Level Agreement is in place for the provision of consultant cover for York Teaching Hospitals NHS Trust Immunology Service with Leeds Teaching Hospitals NHS Trust [IM-INF-SLA IMMUNOLOGY]
- A Service Level Agreement is in place for the provision of advice regarding results on andrology samples received for investigation of infertility from a nominated consultant of assessed competency within York Teaching Hospitals NHS Trust [CY-INF-SLA ANDRO]

h) Select and monitor laboratory suppliers;

It is documented in the job description of the Head BMS for each department that they are responsible for the selection and procurement of new equipment, residual equipment and all other departmental assets across the service. The Head BMS is directly responsible to the Directorate Manager.

i) Select referral laboratories and monitor the quality of their service (see also 4.5);

It is documented within the job description of the Head BMS that they are accountable for the delivery of all the technical services of the department. It is also documented that the clinical lead should continuously develop clinical services in line with best practice and the available evidence



base, directorate and Trust objectives. The Clinical Lead is directly accountable to the Clinical Director and the Head BMS directly accountable to the Directorate Manager.

j) Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;

Head BMS & Operational Managers are responsible for ensuring delivery of ongoing training requirements for all staff to ensure mandatory professional registration. The Operational Managers within the respective departments are responsible for training, but may designate a senior BMS to undertake the role of Training Officer.

k) Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

The job descriptions of the Directorate Manager and Head BMS have documented the responsibility to ensure that quality standards, both those agreed locally and those dictated by national policy are achieved. The job description specifies that the head BMS is responsible for establishing local quality standards, to improve patient care and the efficiency of the department. The Head BMS is directly accountable to the Directorate Manager.

l) Monitor all work performed in the laboratory to determine that clinically relevant information is being generated;

The Head BMS is responsible for providing laboratory workload and statistical data and reports as required; they are also responsible for implementing changes arising from the evaluation of new methodologies and instrumentation in line with service development. A key responsibility of the clinical lead is documented as continuously developing clinical services in line with best practice, the available evidence base, directorate and Trust objectives.

m) Address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4);

This responsibility has been delegated and documented as such to the Directorate Manager. Principle duties of the Directorate Manager are defined within the job description as undertaking the lead role within the directorate for the investigation, reporting and action planning of complaints, litigation issues and adverse incidents within agreed timescales and establishing effective two-way communication, incorporating all staff within the directorate.

n) Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;

It is a documented responsibility of the Head BMS to ensure the delivery of a departmental laboratory service and as such is responsible for essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.

o) Plan and direct research and development, where appropriate.

It is a documented responsibility of the Head BMS to manage and co-ordinate any R&D work for the department including clinical trials and equipment evaluation.

Document References	Q-Pulse Reference
Clinical Director Job Description	LM-INF-JOB-CLIN DIR
Directorate Manager Job Description	LM-INF-JOB-DIR MAN
Departmental Clinical Lead Job Description	LM-INF-JOB-CLIN LEAD
Head BMS Job Description	LM-INF-JOB-BMS8B
Operational Manager Job Description	LM-INF-JOB-BMS8A
IT Systems Manager Job Description	LM-INF-JOB-IT MAN
Quality Manager Job Description	LM-INF-JOB-QM
Deputy Quality Manager & Lead for Health & Safety	LM-INF-JOB- H & S LEAD
IT Coordinator Addendum	LM-INF-JOB-IT COOR
Quality Coordinator Addendum	LM-INF-JOB-QC
Training Officer Addendum	LM-INF-JOB-TO

#### 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:

- a. Ensuring that all laboratory personnel are aware of and comply with the needs and requirements of service users ([4.1.2.2](#)) as well as regulatory and accreditation requirements.
- b. Establishment of the departmental Quality Policy ([4.1.2.3](#)).
- c. Ensuring that quality objectives and plans to achieve these objectives are in place ([4.2.2.4](#)).
- d. Defining responsibilities, authorities and interrelationships of all personnel ([4.1.2.5](#)).
- e. Establishment of effective communication processes with staff and also with the service stakeholders ([4.1.2.6](#)).
- f. Establishment of the role of Laboratory Quality Manager ([4.1.2.7](#)).
- g. Ensuring that management reviews occur on at least an annual basis ([4.15](#)).
- h. Ensuring that staff are competency assessed to provide assurance that they are competent to perform their assigned activities ([5.1.6](#)).
- i. Ensuring that there are adequate resources (see [5.1](#), [5.2](#) & [5.3](#)) to enable the proper conduct of pre-examination, examination and post-examination activities (see [5.4](#), [5.5](#) & [5.7](#)).

##### 4.1.2.2. Needs of Users

Laboratory medicine regularly 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 regularly regarding our service.
- The practice managers are surveyed regularly regarding the service of Laboratory Medicine. The practice managers are also surveyed annually by Cytology alone regarding

the provision of service by Cytology in particular. Cytology runs a rolling programme of visits to the department by practice nurses.

- Hospital and GP users across both the York and Scarborough laboratory sites were surveyed pre and post integration.
- An annual survey is sent out to users of POCT analysers to assess their perception of the service supplied.
- Service level agreements are arranged with other users, including other hospitals and private laboratories, on request.

Previous surveys which have been performed are recorded in the Q-Pulse Document module under audit as in the examples below:

Document References	Q-Pulse Reference
Hospital Based User Survey Report	LM-AUD-HOSP SURV
GP Survey Report	LM-AUD-GP SURVEY
Survey of Laboratory Users York & Scarborough Pre & Post integration	LM-AUD-MERGE SRV
Survey of Laboratory Users York & Scarborough	LM-AUD-ALL USER SURV
NYCCSS User Satisfaction Survey Report	CY-AUD-GP SURVEY
Survey Of Staff Registered for Point of Care Testing	PC-AUD-SURVEY

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

Complaints received from users are fully investigated and any necessary corrective actions undertaken. All adverse incidents concerning the Directorate are encouraged to be reported using the York Teaching Hospitals NHS Foundation Trust Risk Management Tool DATIX according to Trust Adverse Incident Reporting System (AIRS) Policy [YT-POL-AIRS] and are simultaneously recorded in the Q-Pulse CAPA module which has restricted access according to the Laboratory Medicine procedure for On-Line Reporting Of AIRs On Datix [LM-SOP-DATIX] to effectively manage pursuant corrective actions.

Assessment of user feedback is performed by the Quality Manager and reported to the Laboratory Medicine Directorate and Clinical Governance meetings in a format which can be fed back to the individual departments to notify staff and be included in the annual management review.

#### 4.1.2.3. Quality Policy

The Laboratory Medicine Quality Policy featured in section 1.3, is published as a controlled document [LM-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 Laboratory Medicine directorate management team defines the quality objectives of Laboratory Medicine in consultation with the individual disciplines and is responsible for ensuring that plans are made to meet these objectives. The Laboratory Medicine Directorate Strategy document: LM-INF-STRATEGY defines the Directorates strategic plan.

Discipline specific objectives which may relate to the overall directorate strategy are defined within the annual management review. Management review is ongoing at both departmental and directorate level 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 Trust through the Medical Director of the Trust, (Dr. James Taylor) and Clinical Director of Laboratory Medicine, (Dr. Neil Todd) to the Lead Clinician for each discipline. The Clinical Director for Laboratory Medicine acts across the 2 sites and is responsible to the Trust Medical Director for the quality and scope of the service provided by Laboratory Medicine, its Consultant Pathologists and Clinical Scientists.

The Operational Management responsibility runs from the Chief Executive of York Trust through the Corporate Trust Board to the Directorate Manager (Mr Paul Sudworth) and thence to the Head BMS in each discipline. The Directorate Manager for Laboratory Medicine acts across the 2 sites and is responsible for all staff and aspects of service provision and organisation and is also the prime budget holder.

Organisation Charts for Laboratory Medicine can be found within [Appendix 2](#) of this quality manual which details:

- [York Teaching Hospital NHS Foundation Trust \(1\)](#)
- [Laboratory Medicine Management Structure for the Integrated Service \(2\)](#)
- [York & Scarborough Clinical Biochemistry \(3\)](#)
- [York Haematology, Transfusion & Immunology \(4\)](#)
- [York Histology \(5\)](#)
- [North Yorkshire Cytology Screening Service \(6\)](#)
- [York & Scarborough Microbiology \(7\)](#)
- [POCT \(8\)](#)

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

All staff are issued with a job description detailing the general extent and limitations of their responsibilities. These are reviewed annually at appraisal meetings.

Departmental Quality Coordinators are responsible through their Departmental Head BMS to the Laboratory Medicine Quality Manager for issues relating to quality and the maintenance of the QMS. A list of departmental quality coordinators is maintained in Q-Pulse (LM-INF-QUAL COOR)

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

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

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

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 Laboratory Quality Manual.
- Staff must complete a Trust Datix adverse event record as soon as a nonconformity is identified. The named Laboratory Medicine Datix handler must complete a Corrective Action / Preventative 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.
- 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 York Teaching Hospital NHS Foundation Trust is decided at monthly meetings of the Trust Corporate and Executive Boards. These boards are informed by the Trust Patient Safety Group and Health and Safety Committee to whom the Laboratory Medicine groups report.

The main management committees within Laboratory Medicine together with their Terms of Reference are listed within [Appendix 3](#) of this Quality Manual. 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.

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. These meetings are also listed in [Appendix 3](#).

The [Laboratory Medicine Website](#) 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, Trust Leadership walk rounds, MDT participation and via periodic service user feedback surveys.

#### 4.1.2.7. Quality Manager

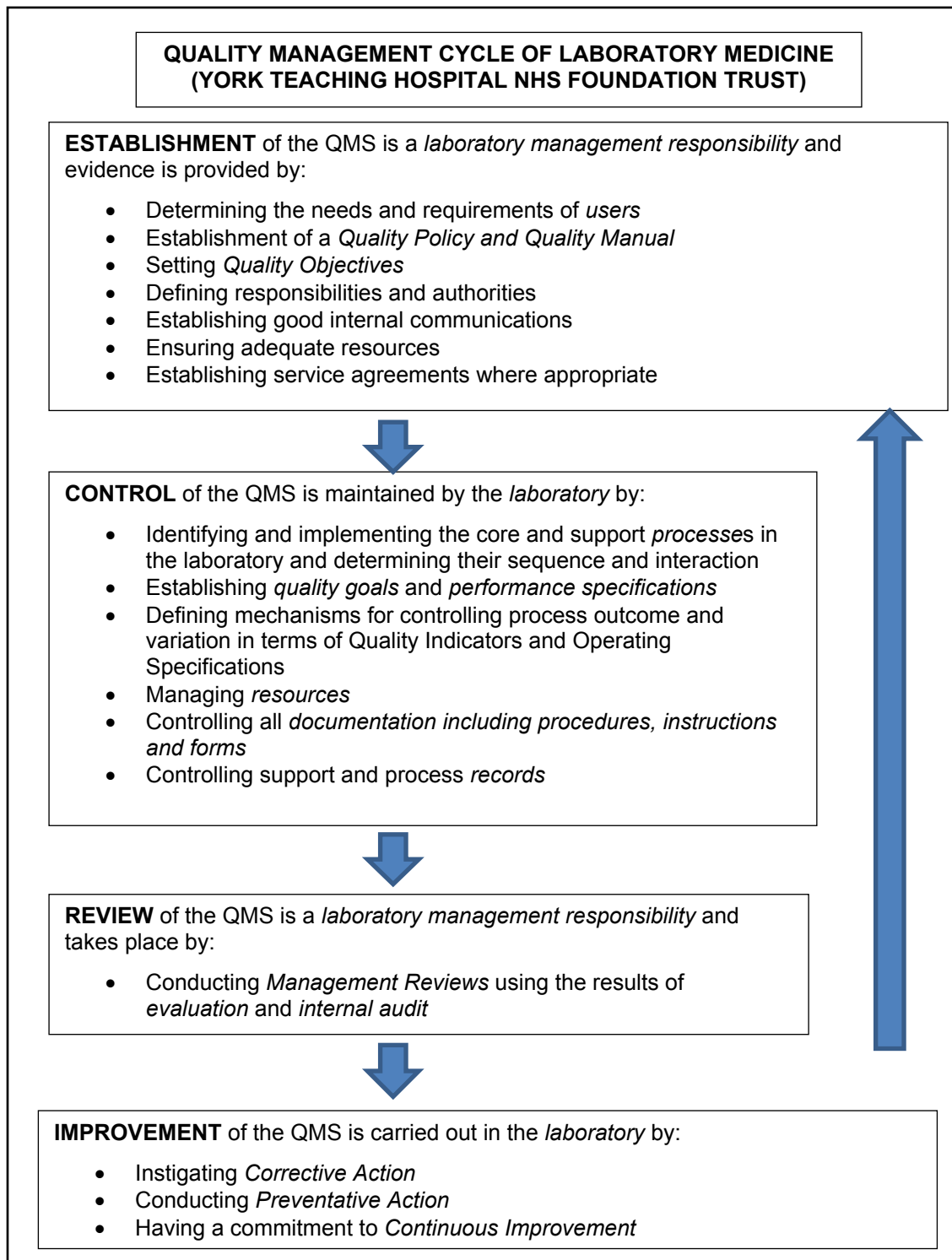
A Laboratory Medicine Quality Manager has been appointed who reports to the Laboratory Medicine Clinical Governance Meeting and the Directorate Management Meeting and has a line of accountability directly to the Directorate Manager. The Quality Manager reports on the requirements of users determined through surveys, analysis of Adverse Incident Reports and consideration of complaints.

The Quality Manager ensures the continuing effective functioning of the Quality Management System 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 Directorate Manager and Head BMSs.

## 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 Laboratory Quality Forum Meeting. The Directorate has chosen Gael Q-Pulse Quality Management Software to help administer the Quality Management System.



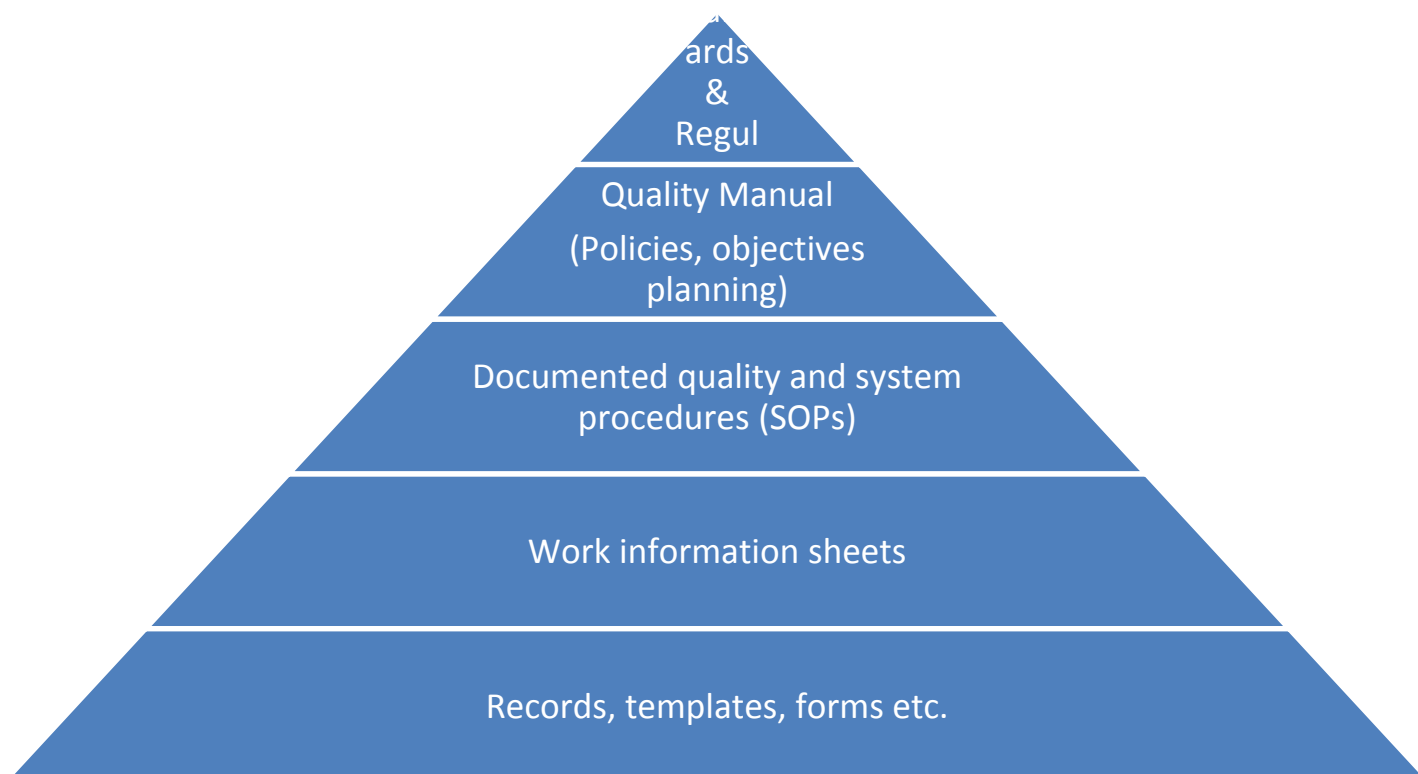
**Figure 2:** The Quality Management Cycle of Laboratory Medicine York Teaching Hospital NHS Foundation Trust.

#### 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](#)), quality objectives ([4.1.2.4](#))

and a Quality Manual (4.2.2.2). Master electronic copies of documentation are held within the document module of Q-Pulse on the Trust Q-Pulse server. 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 on the front of the document and is the responsibility of the person named as responsible in Q-Pulse.



**Figure 3:** Hierarchy of the Laboratory Medicine Documentation System

#### 4.2.2.2 Quality Manual

The quality manual [LM-INF-QUALMAN] defines and describes the QMS in use. It contains a copy of the departments Quality Policy [LM-POL-QUALITY] together with a statement of our aspirations with regard to quality. The Quality Manual outlines the form of the Quality System in operation in Laboratory Medicine, identifying the general arrangements for ensuring that the quality policy is adhered to by staff at all times. The Quality Manual is reviewed annually by the Quality Manager, approved by the Directorate 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 [LM-SOP-QP-DOCS], *The Q-Pulse Document module*. Documents of external origin, such as regulations, standards and text books from which examination procedures are taken are also considered and incorporated into the QMS in accordance with this procedure. Accessibility is further increased by the use of the Q-Pulse web based viewer in accordance with [LM-SOP-QP-DCUVEW], *Using the web based viewer for Q-Pulse*. Only the current, active versions of documents are available at point of use and the unintentional 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 is in need of 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 done in practice at all times. 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.

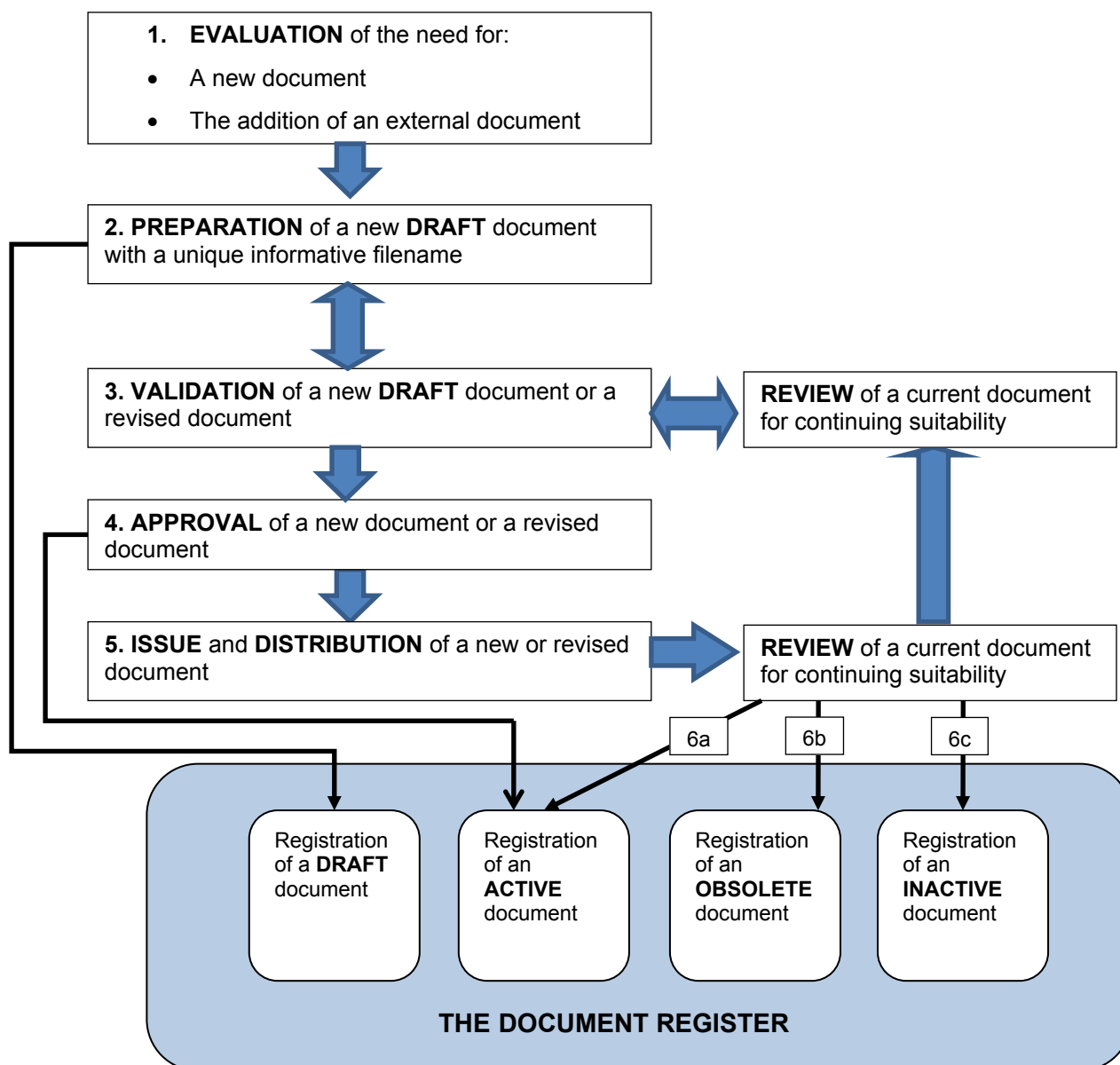
### **Document Revision**

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 period as defined in accordance with [LM-POL-RSDR] *Policy for the Retention, Storage and Disposal of Laboratory Records*. In order to facilitate the use of Web viewer and ensure only current information is available, the directorate aims to keep records and minutes in the active register for a minimum of 2 years and a maximum of 3 years after which they will be archived to the obsolete register in order to facilitate searching particularly on Web viewer.

**Figure 4:** Document Control Procedure



## 4.4 Service Agreements

### 4.4.1 Establishment of Service Agreements

Laboratory Medicine will meet the requirement of ISO15189 with regard to service agreements and work closely with York Teaching Hospitals NHS Foundation Trust Finance Department as

documented in the Laboratory Medicine Policy for the Establishment & Review of Service Level Agreements (SLA).

Document References	Q-Pulse Reference
<a href="#">Laboratory Medicine Policy for the Establishment &amp; Review of Service Level Agreements (SLA)</a>	LM-POL-SLA

To achieve this, Laboratory Medicine 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 Medicine 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 users 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.

### 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 Laboratory Medicine policy. The policy objectives defined are addressed within specific departmental procedures.

Document References	Q-Pulse Reference
<a href="#">Laboratory Policy: Examination by Referral Laboratories</a>	LM-POL-REFERRAL
<a href="#">Biochemistry: Examination by Referral Laboratories</a>	CB-SOP-REFERRAL

<b>Haematology: Examination by Referral Laboratories</b>	<b>HA-SOP-REFERRAL</b>
<b>Haematology: Table of SAS Laboratories &amp; Repertoires</b>	<b>HA-INF-SAS</b>
<b>Microbiology: Selection, Review and Evaluation of Reference Laboratories</b>	<b>MB-SOP-REC-SEND</b>
<b>Referral Laboratory Addresses</b>	<b>MB-SOP-REC-REFLAB</b>
<b>Reporting of Reference Laboratory Results</b>	<b>MB-SOP-REFREPORT</b>
<b>Histology: Consultant Referrals</b>	<b>HI-INF-CON REF</b>
<b>Amending Histopathology Reports</b>	<b>HO-SOP-AMNDRPT</b>
<b>Cytology: Examination by Referral Laboratories</b>	<b>CY-SOP-REFERRAL</b>

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 Trust 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

Laboratory Medicine (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.

Departmental 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 departmental procedure adopted to report referral laboratory results shall take into account 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 York Teaching Hospital NHS Foundation Trust. These policies and procedures inform the Laboratory Medicine documentation:

<b>Document References</b>	<b>Q-Pulse Reference</b>
<b>Laboratory Medicine Policy- Selection and Purchasing of External Services, Equipment, Reagents and Consumables</b>	<b>LM-POL-SUPPLIES</b>
<b>Laboratory Medicine Procedure for Monitoring Suppliers</b>	<b>LM-SOP-SUPPLIERS</b>

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.

The Directorate monitors the performance of suppliers 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 reported to the Laboratory Medicine Management Team meeting to be formally reviewed by inclusion in the Annual Management Review.

## 4.7 Advisory Services

Information for all service users is initially communicated through the official York Trust website, A-Z of Services which includes Laboratory Medicine:

### [York Hospitals Website](#)

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 York Teaching Hospital NHS Foundation Trust 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.

- In Clinical Chemistry these are the clinical scientists and the Consultant Chemical Pathologist.
- In Cytology these are the Consultant Histopathologists and the Consultant BMS.
- In Haematology these are Consultant Haematologists (Plus a Consultant Immunologist).
- In Histology these are Consultant Histopathologists.
- In Microbiology these are Consultant Microbiologists.

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

Document Reference	Q-Pulse Reference
<a href="#">The Handling of complaints in Laboratory Medicine</a>	<a href="#">LM-SOP-COMPLAINT</a>

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

The laboratory investigates all complaints received. All complaints are discussed at the Directorate Management Team, Clinical Governance 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 Trust. (See also 4.14.3)

## 4.9 Identification and Control of Nonconformities

Laboratory Medicine will ensure that the requirements of ISO 15189 are met with regard to 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 Laboratory Medicine Policy for the Identification and Control of Nonconformities [LM-POL-NON-CONFS] 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 Laboratory Medicine SOP for Managing Non Conformities in the Q-Pulse CAPA Module [LM-SOP-QP-CAPA]. Nonconformities are discussed departmentally. In addition, the CAPA records are reviewed by the Quality Manager to detect trends and suggest any further corrective action at the monthly Quality Forum. 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](#); [5.7 Post – Examination Processes](#); [5.9 Release of Results](#).

## 4.10 Corrective Action

Laboratory Medicine will ensure that the requirements of ISO 15189 are met with regard to Corrective Action. The systems and procedures used by Laboratory Medicine 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 Trust 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 by the use of the CAPA module in Q-Pulse following the Laboratory Medicine SOP for Managing Non Conformities in the Q-Pulse CAPA Module [LM-SOP-QP-CAPA]. Target dates for processing and closing off non-conformances are preset depending on the CAPA template assigned for the non-conformance but are usually to be complete within 31 days. The exception is equipment downtime errors which are preset at 7 days.

However, if it is acknowledged that a non-conformance will take longer than its' preset 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 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 by 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 Forum and the Annual Management Review.

## 4.11 Preventative Action

Preventative 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

Preventative action is facilitated by the use of the CAPA module in Q-Pulse following the Laboratory Medicine SOP for Managing Non Conformities in the Q-Pulse CAPA Module [LM-SOP-QP-CAPA]. Again target dates for processing and closing off non-conformances are preset depending on the CAPA template assigned for the non-conformance but are usually to be complete within 31 days. However, if it is acknowledged that a non-conformance will take longer than its' preset 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 preventative action to ensure the non-conformities do not recur

- Implementing preventative action
- Recording the results taken
- Reviewing the effectiveness of the preventative action

Laboratory Management ensure by review that preventative 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 Forum and the Annual Management Review.

## 4.12 Continual Improvement

The Laboratory Medicine Policy for Continual Quality Improvement [LM-POL-QUAL IMP] illustrates how quality improvements can be recognised and ensures that the requirements of ISO 15189 are met with regard to continual improvement. In order to achieve this it will

- Use management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventative 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

Document Reference	Q-Pulse Reference
<a href="#">Policy for Continual Quality Improvement</a>	<a href="#">LM-POL-QUAL IMP</a>

## 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 Medicine Policy for the Retention, Storage and Disposal of Laboratory Records [LM-POL-RSDR] which describes how the directorate 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:

- a) Supplier selection and performance, and changes to the approved supplier list;
- b) Staff qualifications, training and competency records;
- c) Request for examination;
- d) Records of receipt of samples in the laboratory;
- e) Information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts);
- f) Laboratory work books or work sheets;
- g) Instrument printouts and retained data and information;
- h) Examination results and reports;



- i) Instrument maintenance records, including internal and external calibration records;
- j) Calibration functions and conversion factors;
- k) Quality control records;
- l) Incident records and action taken;
- m) Accident records and action taken;
- n) Risk management records;
- o) Nonconformities identified and immediate or corrective action taken;
- p) Preventive action taken;
- q) Complaints and action taken;
- r) Records of internal and external audits;
- s) Interlaboratory comparisons of examination results;
- t) Records of quality improvement activities;
- u) Minutes of meetings that record decisions made about the laboratory's quality management activities;
- v) 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 in order 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 Quality Coordinators. The Quality coordinators are required to familiarise themselves with the Laboratory Medicine QMS utilising this Quality Manual and have received training in auditing techniques from the Quality Manager. Auditors will, wherever possible, be independent of the laboratory area being audited in order to provide objectivity and impartiality.

Document References	Q-Pulse Reference
<a href="#">Basic Use of the Q-Pulse Audit Module</a>	<a href="#">LM-SOP-QP-AUDIT</a>
<a href="#">Advance Use of the Q-Pulse Audit Module</a>	<a href="#">LM-SOP-QP-AUDIT2</a>

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 Laboratory Medicine Quality Forum 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.

Each discipline 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 as part of the Departmental Senior Management Team and Clinical Governance Meetings with attention paid to user surveys and feedback as appropriate and submitted to the monthly Laboratory Medicine Clinical Governance meeting in a format to allow inclusion in the annual management review.

The Laboratory Website includes this information for the users (although it may be revised more frequently if significant changes occur in any department). At times of review, heads of department and clinical leads are advised that review is underway and are expected to review information pertaining to their own departments; this includes sample volumes, collection device and preservative requirements.

#### 4.14.3 Assessment of User Feedback

[See 4.1.2.2 Needs of users](#)

Document References	Q-Pulse Reference
<a href="#">Procedure for Recording of Feedback from Users</a>	<a href="#">LM-SOP- USER FEEDBACK</a>

#### 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](#))
- One to one discussions with senior staff
- Directly to their departmental 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

Document References	Q-Pulse Reference
<a href="#">Laboratory Medicine Quality Improvement Notice</a>	<a href="#">LM-TEM-QIN</a>
<a href="#">Q-Pulse Introduction &amp; Basic Use</a>	<a href="#">LM-SOP-QP-BASIC USE</a>
<a href="#">Laboratory Medicine Procedure for the Control of Change</a>	<a href="#">LM-SOP-QP-COC</a>
<a href="#">Managing Non Conformances in the Q-Pulse CAPA Module</a>	<a href="#">LM-SOP-QP-CAPA</a>
<a href="#">Laboratory Procedure for Recording Quality Improvement Recommendations</a>	<a href="#">LM-SOP-QUAL IMP</a>

Records of suggestions made, evaluation, feedback given and action taken by the management are maintained by the Laboratory Medicine Procedure for the Control of change [LM-SOP-QP-COC].

All standard operating procedures are reviewed regularly as per the requirements of the document control system ([4.3](#)) in order to ensure the accuracy of the content and also as an opportunity to

identify potential sources of improvement in quality management or technical practices. All 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](#)

#### 4.14.6 Risk Management

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

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 adverse incidents concerning the Directorate are encouraged to be reported using the York Teaching Hospitals NHS Foundation Trust Risk Management Tool DATIX according to Trust Adverse Incident Reporting System (AIRS) Policy [YT-POL-AIRS] and are simultaneously recorded in the Q-Pulse CAPA module, which has restricted access, according to the Laboratory Medicine procedure for On-Line Reporting Of AIRs On Datix [LM-SOP-DATIX] to effectively manage pursuant corrective actions and amend work processes. All DATIX incidents are reviewed monthly by the Quality Manager and trends reported to the Laboratory Medicine Directorate Team and Clinical Governance meetings in a format that can then be presented at the Annual Management Review.

Any significant or high risks are recorded on the Laboratory Medicine Risk Register in accordance with Trust Risk Management Framework [YT-POL-RISK MAN] and the Laboratory Medicine Risk Strategy [LM-POL-RISK STRAT]. The Risk Register is updated regularly by the Quality Manager in conjunction with the Directorate Healthcare Governance Lead and presented by the Directorate Manager at the Trust Performance Assurance Meeting where progress taken to mitigate the risk are discussed and potentially raised to the corporate risk register for action.

Document References	Q-Pulse Reference
<a href="#">Procedure For Conducting Risk Assessments (Inc. COSHH)</a>	<a href="#">LM-SOP-RISKASS</a>
<a href="#">Laboratory Medicine Risk Strategy</a>	<a href="#">LM-POL-RISK STRAT</a>
<a href="#">Laboratory Medicine Risk Register</a>	<a href="#">LM-INF-RISK REG</a>

#### 4.14.7 Quality Indicators

The laboratory has established a number of 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 Directorate is working towards the Key Performance Indicators proposed by the Royal College of Pathologists in July 2013.

The Directorate Manager attends regular Performance Assurance Meetings with the corporate team to review Laboratory Medicine's performance dashboard (Signal). Items reviewed include, productivity, key turnaround times (e.g. results reported to Emergency Department within 4 hours), actual top ten tests workload against planned bed directorate workload, 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:

Document References	Q-Pulse Reference
<a href="#">Laboratory Medicine Policy for Quality Indicators</a>	<a href="#">LM-POL-QUAL IND</a>
<a href="#">Haematology: Quality Indicators</a>	<a href="#">HA-SOP-QUAL IND</a>

Quality Indicators are discussed at departmental staff meetings and reported to the Directorate Management Team and Clinical Governance Meeting monthly. Quality indicators are reviewed as part of the Annual 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 Directorate Management Team Meeting and other meetings within the Directorate as deemed relevant and incorporated into the Annual Management Review. Prior to 2016 Assessment reports were entered in the Assessment section of the document module of Q-Pulse and CAPA raised independently through the CAPA module.

See [4.14.1 General](#)

See [4.10 Corrective Action](#)

See [4.11 Preventative Action](#)

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

Laboratory Medicine reviews the QMS on an annual basis to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

The review elements includes:

[Review input \(4.15.2\)](#)

[Review activities \(4.15.3\)](#)

[Review output \(4.15.4\)](#)

Document References	Q-Pulse Reference
<b>Policy for Management Review</b>	<b>LM-POL-MAN REV</b>

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

### 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 laboratories 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 and submitted for approval to the Laboratory Medicine Management Team via the Q-Pulse Document Module subsequent to distribution to all laboratory staff. The actions and quality objectives generated as a result of the review are monitored via the Laboratory Medicine Quality Forum.

Document References	Q-Pulse Reference
<a href="#">Annual Management Review Report</a>	<a href="#">LM-REC-AMR</a>

## 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 York Teaching Hospital NHS Foundation Trust. Recruitment, Selection and Appointment – Additional Guidance for Managers [YT-INF-RECRUIT] is available on the Trust Intranet site Staff Room. Additional Laboratory Medicine documentation supplements this guidance to fulfil the requirements of ISO 15189.

Staff are registered in accordance with current national legislation and guidelines. The Trust Human Resources department checks the registration status of all doctors within the Trust; the doctors must show their GMC renewals to the Governance Manager in accordance with the Trust Professional Registration Policy [YT-POL-REGISTRATION]. Technical and ancillary staff are accountable to the Directorate Manager. A HCPC registration check of credentials is performed prior to the employment of Clinical Scientists and Biomedical Scientists. These staff may also present their HCPC registration certificates within Laboratory Medicine for recording in Q-Pulse, however the certificate cannot be taken as evidence that the employee is still on the register. An annual staff HCPC registration check is performed [LM-AUD-HCPC CHK].

The nature and number of staff required by the Directorate is kept constantly under review (see [Review input \(4.15.2\)](#), directorate and senior management team meetings) as new working practices and organizational structures are developed. Indirect evidence of inappropriately low staffing levels may include the number of meetings cancelled, decisions minuted 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 Trust vacancy control procedures.

Document References	Q-Pulse Reference
<a href="#">The Training Module in Q-Pulse</a>	<a href="#">LM-SOP-QP-TRAIN</a>

### 5.1.2 Personnel Qualifications

A job description and personnel specification sets 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. 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)

Electronic copies of each individual's job descriptions are embedded as attachments in the properties section of their personnel records in the People module of Q-Pulse. Each individual is also given a hardcopy of his or her job description. The exceptions to this are medical staffs that only have a hard copy stored.

Contracts are kept in hard copy only in locked filing cabinets in room S1.35 in the main office on the first floor of Laboratory Medicine or in the Laboratory Office at Scarborough.

### 5.1.4 Personnel Introduction to the Organizational Environment

Staff induction consists of two elements within Laboratory Medicine.

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

Staff induction gives information on:

- The individual departments, Laboratory Medicine in general, and York Teaching Hospital NHS Foundation Trust
- 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:

Document References	Q-Pulse Reference
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<b>Clinical Biochemistry: Induction Document</b>	<b>CB-INF-INDUCTION</b>
<b>Blood Sciences Reception MLA: Induction Document</b>	<b>OR-INF-INDUCTION</b>
<b>Cytology: Induction Document</b>	<b>CY-INF-INDUCTION</b>
<b>Haematology, Immunology, Blood Transfusion: Induction Document</b>	<b>HA-INF-INDUCTION</b>
<b>Histopathology: Induction Document</b>	<b>HI-INF-INDUCTION</b>
<b>Microbiology: Induction Document</b>	<b>MB-INF-INDUCTION</b>
<b>Mortuary: Induction Document</b>	<b>MO-INF-INDUCTION</b>

### 5.1.5 Training

Laboratory Medicine has a training policy which states it's commitment to providing continuing training and education for all members of staff. The policy states that personnel undergoing training shall be supervised at all times. The effectiveness of the training programme is kept constantly under review at Training Officer, Directorate 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](#))

The Training Officers within each department ensure that all staff attends the training deemed mandatory by the Trust. 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.

<b>Document References</b>	<b>Q-Pulse Reference</b>
<b>Laboratory Medicine Training Policy</b>	<b>LM-POL-TRAINING</b>

Laboratory Medicine provides training for all personnel which include the following areas:

- a) The Quality Management System: All new starters receive an introductory presentation from the Quality Manager covering the Quality Management System within Laboratory Medicine [LM-INF-QUAL-RISK]. All trainee BMS staff receives a tutorial from the Quality Manger on general principles of Quality and Risk Management based on the presentation [LM-INF-QMTRAINEE]. The Quality Manager gives individual training on Q-Pulse as relevant to the staff member's role on a one to one basis.
- b) 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:



Document References	Q-Pulse Reference
Clinical Biochemistry Training Manual	CB-INF-TRAINMAN
Clinical Biochemistry MLA/Clerical Training Manual	OC-INF-TRAINMAN
Cytology Training Manual	CY-INF-TRAINMAN
Cytology MLA Training Manual	CY-INF-TRAINMLA
Haematology Training Manual	HA-INF-TRAINMAN
Histopathology Training Manual	HI-INF-TRAINMAN
Microbiology Training Manual	MB-INF-TRAINMAN
Mortuary Training Manual	MO-INF-TRAINMAN

- c) The applicable laboratory Information System: The Laboratory IT Systems Manager and nominated Departmental 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.
- d) 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 e-Learning Hub. Further departmentally related training is conducted within the departments of Laboratory Medicine. 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].
- e) 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 Laboratory Medicine 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:**

**A:** Written Assessment e.g. Q & A.

**B:** Direct Observation of routine work processes & procedures, including all applicable safety practices.

**C:** Direct Observation of equipment maintenance and function

**D:** Review of work records

**E:** Examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples.

**F:** Assessment of problem solving skills.

The 'Template for Competency Assessment' [LM-TEM-CA] has been developed to create generic Laboratory Medicine 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) is recorded in the Q-Pulse Training Module and embedded for the retention by Laboratory Medicine. Signed hardcopy records of competency assessments are issued to staff. These hardcopy records are not kept by the laboratory and may be removed by staff when they leave.

The Q-Pulse events are renewable as appropriate, (commonly 2 years) and scheduled in Q-Pulse accordingly. Management of the renewals and retraining is assisted by Q-Pulse, which sends messages out to remind trainees of scheduled requirements and, if these are ignored, by escalation messages to the Training Officer.

Competency assessment for professional judgement with regard to 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 staff in Laboratory Medicine partakes in an Annual Joint Review or Personal Development Review (PDR) in line with the Trust Appraisal Guidance [YT-INF-APPRAISAL]. The Appraisal Framework embeds the competencies from the Agenda for Change KSF (Knowledge & Skills Framework), the Trust Values, and the Personal Responsibility Framework.

PDR takes into consideration:

- a) The stated objectives and plans of the Trust and Laboratory Medicine.
- b) The job description of the member of staff.
- c) The personal objectives of the staff member.
- d) The training and development needs of the staff member.

The staffs performing the PDR receive in-house training from the Trust which is recorded in the Q-Pulse training module (see 5.1.7 Competency Assessment). Training needs analysis is performed on completed PDR reports and education/training is allocated as required within budgetary constraints.

PDR is managed through use of the 'Reviews' section in each staff member's personnel record in the Q-Pulse People Module. PDR is managed through use of the 'Reviews' section in each staff member's personnel record. PDR outcomes are recorded on forms for which templates are used. The PDR reports are regarded as confidential between appraiser and appraisee and stored accordingly. The objectives, (PDPs or Personal Development Plans), however, are not confidential as these are required for training needs analysis and are embedded in each person's 'Reviews' section.

### 5.1.8 Continuing Education and Professional Development

In order 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. Laboratory Medicine has a documented policy:

Document References	Q-Pulse Reference
<a href="#">Continuing Professional Development Policy</a>	<a href="#">LM-POL-CPD</a>

Staff should keep a personal portfolio in order 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. In addition, all staff have a training record on Q Pulse administered by the training officer.

Educational and training resources include:

- a) 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.
- b) Laboratory Medicine has its own seminar room (York - S1.16) that has video conferencing facilities for cross site meetings and training sessions. Access to a quiet room for study is also available departmentally.
- c) Staffs are encouraged to attend instrument training courses, user group meetings, symposia and conferences. There is also an active CPD group within Laboratory Medicine that organises in-house lunchtime presentations and evening meetings.
- d) Financial support is given to staff, within the budgetary constraints.

The effectiveness of the CPD programme is kept under review at the Pathology CPD Group, Training Officer, Directorate and Senior Management Team Meetings as new working practices and organizational structures are developed.

### 5.1.9 Personnel Records

The Directorate utilizes the functionality of the Q-Pulse People and Training modules to maintain many personnel records. 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 Medicine Policy.

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 Medicine 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 directorate meetings and reviewed at the Annual Management Review (see [4.15.2](#)). If insufficient working space is highlighted it is incorporated onto the Directorate Risk Register.

A general risk assessment of the environment in Laboratory Medicine is carried out 2 yearly as a minimum in each discipline on each site according to the following Laboratory Medicine 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 Medicine 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
<b>Procedure For Conducting Risk Assessments (Inc. COSHH)</b>	<b>LM-SOP-RISKASS</b>
<b>Undertaking A Health and Safety Inspection</b>	<b>LM-SOP-HSINSP</b>
<b>Laboratory Medicine Safety Policy</b>	<b>LM-POL-SAFETY</b>
<b>Laboratory Medicine Security</b>	<b>LM-POL-SECURITY</b>
<b>Local Rules</b>	<b>LM-POL-LOCAL</b>

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 checks are maintained within the Health & Safety section of the Q-Pulse Audit Module.

### 5.2.2 Laboratory and Office Facilities

Laboratory Medicine 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 with regard to such hazards as electricity, high and low temperatures, inflammables, ionising radiation etc.
- Communication systems within Laboratory Medicine 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
<a href="#">The Laboratory Medicine Policy for the Retention, Storage and Disposal of Laboratory Records</a>	<a href="#">LM-POL-RSDR</a>
<a href="#">Policy for the Retention, Storage and Disposal of Laboratory Samples</a>	<a href="#">LM-POL-RSDS</a>

[LM-POL-RSDR] describes how the directorate 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 directorate 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:

Document References	Q-Pulse Reference
<a href="#">Waste Management Procedure</a>	<a href="#">LM-SOP-WASTE</a>
<a href="#">Local Rules</a>	<a href="#">LM-POL-LOCAL</a>

#### 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 the site. The laboratory is provided with:

- Toilet facilities, (♂ & ♀) are available for staff on all three floors of Laboratory Medicine and in Mortuary. Staff toilets are available on the 1<sup>st</sup> floor of Scarborough Laboratory Medicine.
- Male and female showers are available in Mortuary.
- A rest area is available for use on the 1<sup>st</sup> floor of Laboratory Medicine at York and in the Mortuary, room J0.31. A rest area is located on the 1<sup>st</sup> floor of Scarborough Laboratory Medicine. 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 1<sup>st</sup> floor at both York and Scarborough sites and the Mortuary.
- 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.
- Laboratory Medicine has its own seminar room (York - S1.16) that has video conferencing facilities for cross site meetings and training sessions. Access to a quiet room for study is also available departmentally.

### 5.2.5 Patient Sample Collection Facilities

At York and Scarborough sites phlebotomy is no longer managed by Laboratory Medicine the function is now being held by Specialist Medicine. Laboratory Medicine 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 Laboratory Medicine at York are located on the ground floor in the outpatient department of the hospital and at the ASDA supermarket. The phlebotomy service for Scarborough is located within the entrance area to the Laboratories. There is full patient access to Phlebotomy at both the York and Scarborough hospital sites, including disabled access. The waiting area is separate from the phlebotomy room where samples are procured. Within the phlebotomy room each phlebotomy station is segregated off so that patients are afforded suitable privacy.

Access to toilet facilities including for disabled persons is situated very close to the phlebotomy facility in the OPD department. Scarborough Laboratory Medicine has toilet facilities and access for disabled persons, affiliated to the Phlebotomy facility within the Directorate facility.

The phlebotomy areas have and maintain appropriate first aid materials for both patient and staff needs. 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 facility adjacent to Laboratory Medicine. This is available ONLY by prior booking through the Cytology laboratory (01904 726332). 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.

#### **Mortuary Visitors York & Scarborough (Viewers of the deceased):**

Viewers of the deceased have access to a unisex toilet, at York it has been designated suitable for the disabled (room J0.35), the Scarborough toilet is not designated disabled but is on the ground

floor. Visitors can also make use of waiting rooms with soft furnishings. The 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 Trust Estates & Facilities. Staff are required to maintain good housekeeping throughout the laboratory at all times. The environment is required to be kept clean and tidy, in a manner that is compatible with the level of safety required for the operation of a laboratory handling samples for biological examination.

The Trust Health and Safety Manager performs an annual inspection of the Laboratory Facilities on both the York & Scarborough sites in conjunction with the Laboratory Medicine Health & Safety Representatives 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 departmental 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 through the use of cabinets and the designated category 3 room in the Microbiology department.

Quiet environments are provided in certain laboratory areas e.g. histology dissection room and cytology screening 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
<a href="#">Laboratory Medicine Policy for Equipment Handling</a>	<a href="#">LM-POL-EQUIPMENT</a>
<a href="#">Disposal of Equipment</a>	<a href="#">LM-SOP-EQUIPDIS</a>

[See 4.6](#) 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 departmental meeting. With regard to POCT equipment, this is assessed by the POCT co-ordinator for York Trust, in conjunction with the POCT committee. Only equipment fit for its intended purpose is used by the Directorate 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 in order to ensure that systems are kept up to date and

prior to service quality being impaired due to poor performance. Increasingly the laboratory is obtaining major equipment as part of a Managed 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.

Laboratory Medicine 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.

Document References	Q-Pulse Reference
<a href="#">The Equipment Module In Q-Pulse</a>	<a href="#">LM-SOP-QP-EQUIPMT</a>

### 5.3.1.2 Equipment Acceptance Testing

Upon installation and prior to use Laboratory Medicine 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 Medicine policy and guidelines. Before new electrical equipment is put into routine use it is suitably electrically safety tested as per Trust requirements.

Document References	Q-Pulse Reference
<a href="#">Policy And Guidelines For Change Control &amp; Validation (Equipment/ Materials/IT/Staff)</a>	<a href="#">LM-POL-VALIDATE</a>
<a href="#">Laboratory Medicine Equipment Acceptance Template</a>	<a href="#">LM-TEM-EQUIP ACCEPT</a>

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 manufacturers 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 takes into account 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:

- a) The conditions of use and the manufacturer's instructions are taken into account ([see 5.3.1.3](#))
- b) A record of the metrological traceability of the calibration standard and the traceable calibration of the equipment is maintained
- c) Verification of the required measurement accuracy and the functioning of the measuring at defined intervals
- d) Recording the calibration status and date of calibration
- e) Ensuring that, where correction factors are applied as a result of calibration, any previous calibration factors are suitably updated
- f) 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 manufacturer's or maintenance companies who are themselves able to prove competence to calibrate the equipment, by holding certification against ISO 17025. Such documentation is acceptable as long as 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 preventative 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:

Document References	Q-Pulse Reference
<a href="#">Blood Transfusion Equipment Downtime Error Log</a>	<a href="#">BT-TEM-DOWNTIME LOG</a>
<a href="#">Equipment Error Logsheet</a>	<a href="#">LM-TEM-EQUIP ERR</a>

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.

Document References	Q-Pulse Reference
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](#)).

Laboratory Medicine ensures that reasonable measures are taken to decontaminate equipment before service, repair or decommissioning. A Declaration of Contamination Status form [LM-TEM-DECONFIRM] 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-DECONFIRM
Disinfection and Spillages - Clinical Biochemistry	CB-SOP-DISINFECT
General disinfection and disposal of clinical waste	CY-SOP-P-CLINWAS
Disinfection - Haematology, Transfusion & Immunology	HA-SOP-DISINFECT
Histopathology Disinfection Procedure	HI-SOP-DISINFECT
Preparation and Guidelines for Use of Disinfectants	MB-SOP-H&S-DIS
Disinfection Procedure	MO-SOP-DISINFECT

### 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 also to MHRA or HSE as necessary.

Document References	Q-Pulse Reference
<a href="#">On-Line Reporting Of AIRs On Datix</a>	<a href="#">LM-SOP-DATIX</a>
<a href="#">Managing Non Conformances in the Q-Pulse CAPA Module</a>	<a href="#">LM-SOP-QP-CAPA</a>
<a href="#">MHRA Incident Reporting (Equipment)</a>	<a href="#">LM-SOP-MHRAREPRT</a>
<a href="#">Guide To RIDDOR Reporting.</a>	<a href="#">LM-INF-RIDDOR</a>

### 5.3.1.7 Equipment Records

Laboratory Medicine 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:

- a) The identity/type of the equipment
- b) The manufacturer's name, model and serial number or other unique identifier
- c) Contact information for the supplier or the manufacturer\*
- d) Date of receiving and date of entering into service
- e) Current location by room number within the Trust
- f) Condition when received (e.g. new, used or reconditioned)
- g) A link to manufacturer's instructions\*
- h) A reference to the record that confirmed the equipment's initial acceptability for use when the equipment is incorporated in the laboratory\*
- i) Maintenance carried out and the schedule for preventative maintenance
- j) 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.\*
- k) 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.

Departmental procedures are in place within Laboratory Medicine for the reception, storage, acceptance testing and inventory management of reagents and consumables driven by the Laboratory Medicine policy in order to conform to the tertiary sub clauses of ISO 15189.

Document References	Q-Pulse Reference
<b>Directorate Policy: Reception, Storage, Acceptance Testing and Inventory Management of Reagents and Consumables</b>	<b>LM-POL-RECEIPT</b>
<b>Clinical Biochemistry: Reception, Storage, Acceptance Testing and Inventory Management of Reagents and Consumables</b>	<b>CB-SOP-RECEIPT</b>
<b>Receipt &amp; Storage of Reagents &amp; Consumables for use in the Haematology Department</b>	<b>HA-SOP-RECEIPT</b>
<b>Immunology: Reception, Storage, Acceptance Testing and Inventory Management of Reagents and Consumables</b>	<b>IM-SOP-RECEIPT</b>
<b>Blood Transfusion: Reagent Diary</b>	<b>BT-SOP-READIARY</b>
<b>Microbiology: Management of Reagents, Calibration and Quality Control Materials</b>	<b>MB-SOP-MANREAG</b>
<b>Histology: Reception, Storage and Inventory Management of Reagents and Consumables</b>  <b>Specific information on acceptance testing can also be located in departmental documentation</b>	<b>HI-SOP-RECEIPT</b>  <b>HI-POL-IHC VERIFICATION</b> <b>HI-POL-SS VERIFICATION</b> <b>HI-POL-QUALITY and individual SOPs</b>

<b>Cytology: Receipt of Consumables</b>	<b>CY-SOP-RECEIPT</b>
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### 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
<a href="#">York Stores Risk Assessment</a>	<a href="#">LM-HSR-YORK STORE</a>
<a href="#">Pharmacy Stores Risk Assessment</a>	<a href="#">PC-HSR-PHARM-STORE</a>

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 also to MHRA or HSE if necessary.

Document References	Q-Pulse Reference
<a href="#">On-Line Reporting Of AIRs On Datix</a>	<a href="#">LM-SOP-DATIX</a>
<a href="#">MHRA Incident Reporting (Equipment)</a>	<a href="#">LM-SOP-MHRAREPRT</a>

## 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 in order to conform to ISO 15189:

- a) Name of the reagent or consumable
- b) Manufacturer's name and batch code or lot number
- c) Contact details for the item supplier or manufacturer
- d) Date of receipt, expiry (if applicable), first use and where applicable the date the material was taken out of service.
- e) Condition when received (e.g. acceptable or damaged)
- f) Manufacturer's instructions (if applicable)
- g) Records of confirmation of acceptance for use.
- h) Records that confirm the reagents or consumables on-going acceptance for use.
- i) 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

Laboratory Medicine has 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](#)). The Laboratory Medicine policy, Laboratory Medicine Website Access and Amendments [LM-POL-WEBSITE] provides information on the website and how information is controlled.

### 5.4.2 Information for Patients and Users

As a minimum, this information includes:

- a) Location of the laboratory
- b) Types of clinical service provided, including the examinations referred to other laboratories
- c) The laboratory opening hours
- d) 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
- e) Instructions for completion of request forms
- f) Instructions for preparation of the patient
- g) Instructions for patient collected samples
- h) Instructions for sample transportation, including any special handling needs
- i) Any requirements for patient consent (if required)

- j) Criteria for the acceptance and rejection of samples
- k) Factors known to significantly affect the performance of the examination or the interpretation of the results.
- l) Availability of clinical advice on ordering examinations and on the interpretation of results
- m) Laboratory's policy on the protection of personal information (Trust Information Governance Policy)
- n) 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

Scarborough, Bridlington, Malton and Whitby GP surgeries request laboratory investigations using the ICE Order Communications Module. Ward Order Communications is available through CPD within the York Hospital site. 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. Laboratory Medicine is currently expanding the use of electronic requesting across all areas of the York and Scarborough sites in conjunction with users and the Trust Systems and Network Team.

Users are encouraged to comment on requesting during surveys. Requesting is also discussed when Laboratory Managers visit surgeries for face-to-face meetings with users. Further to this, several years ago one GP designed a system for printing out request forms by populating a word template from his surgery's LIMS system (then Torex). The Laboratory has cooperated enthusiastically with this development and encouraged other surgeries to use the system, which many now do.

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:

- a) Patient identification: This includes; patient name, gender, date of birth, patient location details, unique identifier (e.g. ideally the NHS number)
- b) 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.
- c) Type of primary sample and anatomic site of origin, where relevant (e.g. within histopathology).
- d) Examinations requested.
- e) Clinically relevant patient information (e.g. patient's family history, travel and exposure history, communicable diseases).
- f) Date and (where relevant) time of primary sample collection.
- g) Date and time of sample receipt.

The Trust policy available for all staff for filling in request forms and labelling samples was written by Laboratory Medicine 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
<b>Laboratory Medicine Policy for Filling in Request Forms &amp; Labelling Samples</b>	<b>LM-POL-LABELLING</b>

Requests can be made to Laboratory Medicine 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
<b>Clinical Biochemistry: Add on Tests</b>	<b>CB-SOP-ADD-ON</b>
<b>Adding On Tests in Haematology &amp; Immunology</b>	<b>HA-SOP-ADD ON TESTS</b>
<b>Requests to add on microbiology tests to samples already received</b>	<b>MB-SOP-ADD ON TESTS</b>

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

Laboratory Medicine 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 York Trust website ([See General Information 1.4 Information for Users](#)).

Please note Laboratory Medicine 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:

- a) The confirmation of the identity of the patient from whom the sample is to be collected
- b) The verification that the patient meets pre-examination requirements (e.g. fasting status, medication status)
- c) 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
- d) Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives
- e) Instructions for labeling 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 labeling samples [LM-POL-LABELLING]

- f) Recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording the collection time
- g) Instructions for the proper storage conditions before collected samples are delivered to the laboratory
- h) 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 Request 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](#) Instructions for pre-collection activities.

#### 5.4.5 Sample Transportation

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

Please note Laboratory Medicine 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
Model Rules for Porters Regarding Laboratory Medicine (Staff Room)	LM-POL-MR PORTRS

Each department 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 general 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
<b>Blood Sciences Specimen Reception: Monitoring the Transportation of Samples</b>	<b>SR-SOP-TRANSPORT</b>
<b>Monitoring the Transportation of Microbiology Samples</b>	<b>MB-SOP-TRANSPORT</b>
<b>Cross-Site Comparability of Examination Results</b>	<b>MB-SOP-COMPARE</b>
<b>Cytology: Monitoring the Transportation of Samples</b>	<b>CY-SOP-TRANSPORT</b>
<b>Histology: Monitoring the Transportation of Samples</b>	<b>HI-SOP-TRANSPORT</b>

#### 5.4.6 Sample Reception

Laboratory Medicine (York) 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 take 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 2<sup>nd</sup> floor of the Laboratory Medicine block, Cytology, Histology, and Microbiology all have their own reception areas.

Laboratory Medicine (Scarborough) has three 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 supplies 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 Histology and Cytology samples for transfer to York. The Microbiology sample reception area is on the first floor.

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

- a) Samples are unequivocally traceable, by request and labeling to an identified patient or site. With the exceptions of Histology and Cytology (non-gynae), 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.

- b) Laboratory developed criteria for acceptance or rejection of samples are applied.
- c) 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 chooses 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.

Department	Document References	Q-Pulse Reference
Biochemistry/Haematology	Sample Labelling and Checking Procedures	SR-SOP-RECEPTION
Blood Transfusion	Samples & Requests	BT-SOP-SAMPLES
Cytology	Receipt, unpacking and initial processing of cervical samples	CY-SOP-P-REC CYT
	Receipt and numbering of non-gynaecological specimens	CY-SOP-P-NG REC
	Handling of unlabelled and mislabelled cytology specimens	CY-SOP- P-MISMATC
Histology	Reception and Unpacking of Specimens	HI-SOP-RECEPTION
Microbiology	Specimen Processing Reception Bench	MB-SOP-REC-SORT
	Microbiology Specimen Reception	SMB-SOP-MICROREP

- d) All departments record the request form and specimen details of all samples received electronically using the iSoft-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.

Department	Document References	Q-Pulse Reference
Biochemistry/ Haematology	Request Entry on Telepath	SR-SOP-REQENTRY
Cytology	Non-Gynaecological Cytology Entry	CY-SOP-O-NGENT
	Gynaecological Cytology Entry	CY-SOP-O-GYENT
Histology	Request Entry on Telepath	HI-SOP-REQENTRY
Microbiology	Request Entry on Telepath	MB-SOP-TP-ENTRY

- e) 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 might be any doubt about a sample, reception staff consult a relevant member of the laboratory clinical staff ([see 5.1.6 Competency Assessment](#)).

- f) 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.

Department	Document References	Q-Pulse Reference
Biochemistry/Haematology	Dealing With Urgent Samples	SR-SOP-RECEPTION
Cytology	Receipt, unpacking and initial processing of cervical samples Handling of Urgent FNA's	CY-SOP-P-REC CYT CY-SOP-P-URGFNA
Histology	Dealing With Urgent Samples	HI-SOP-URGENT
York & Scarborough Microbiology	Specimen Processing Reception Bench Microbiology Specimen Reception	MB-SOP-REC-SORT SMB-SOP-MICROREP

#### 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

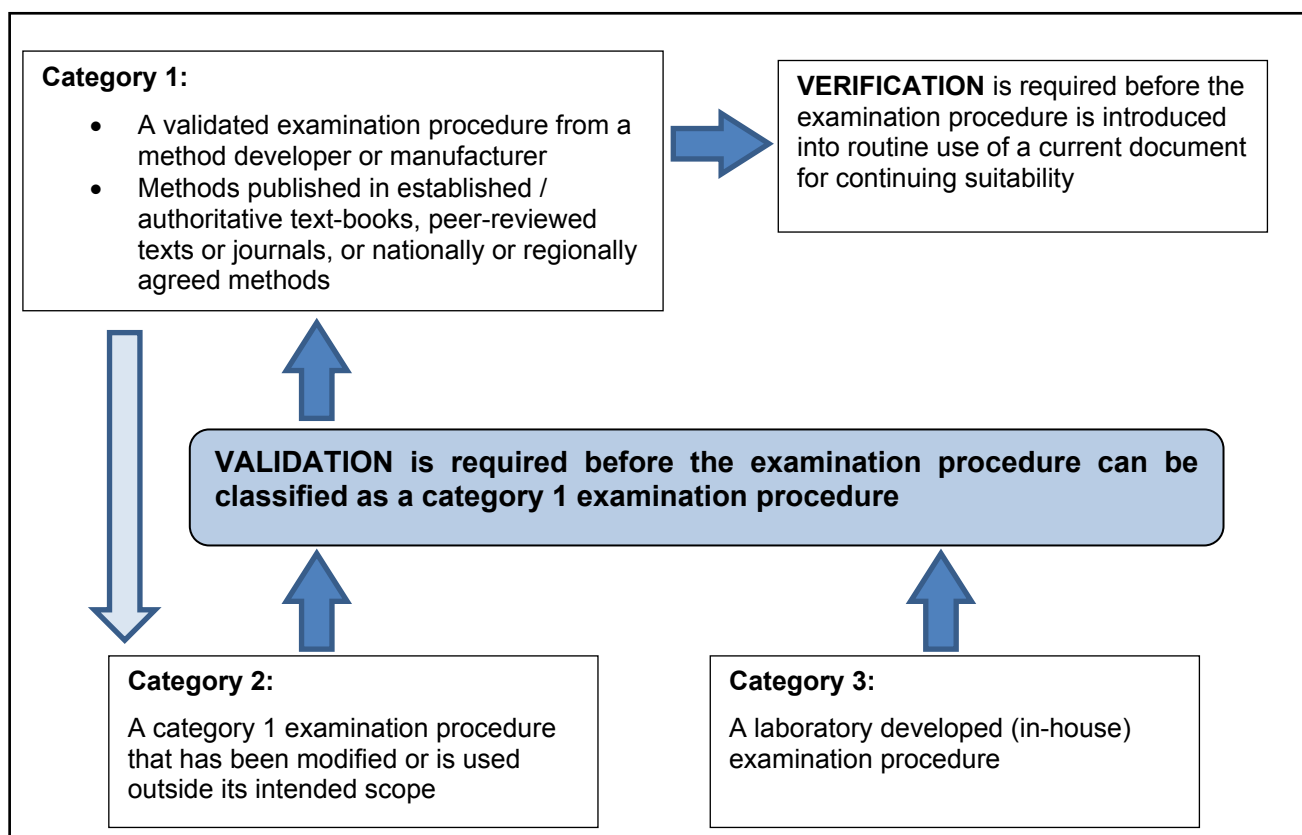
Time limits for requesting additional or further examinations on already received samples are contained within individual SOPs and also provided to users via the official York Trust website ([See General Information 1.4 Information for Users](#)).

## 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.



**Figure 5: Clarification of requirement for Verification and Validation Status within Laboratory Medicine (York Teaching Hospital NHS Foundation Trust)**

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; initialing 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 Laboratory Medicine in order to confirm the performance specification, before being introduced into routine use. The verification is guided by the Laboratory Medicine 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
Policy And Guidelines For Change Control & Validation (Equipment/ Materials/IT/Staff)	LM-POL-VALIDATE
Procedure for the Evaluation of a Method	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 Laboratory Medicine 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](#)), details which examination procedures Laboratory Medicine 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 Laboratory Medicine's 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](#). [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

Laboratory Medicine 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
<a href="#">Clinical Chemistry: Measurement of Uncertainty</a>	<a href="#">CB-SOP-UNCERTAINTY</a>
<a href="#">Haematology: Measurement of Uncertainty</a>	<a href="#">HA-SOP-UNCERTAINTY</a> <a href="#">HA-INF-UNCERT</a> <a href="#">CO-INF-UNCERT</a>

<b>Blood Transfusion: Measurement of Uncertainty</b>	<b>BT-SOP-UNCERTAINTY</b>
<b>Immunology: Measurement of Uncertainty</b>	<b>HA-SOP-UNCERTAINTY IM-INF-UNCERT</b>
<b>The Uncertainty of Measurement in Microbiology</b>	<b>MB-SOP-UNCERTAINTY</b>
<b>Factors Affecting Uncertainty of Results</b>	<b>HI-POL-UNCERTAINTY</b>
<b>Cytology: Measurement of Uncertainty</b>	<b>CY-SOP-UNCERTAINTY</b>

### 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 Information 1.4 Information for Users](#)). 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 have automatic 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
<b>Control of Change using the Q-Pulse CAPA Module</b>	<b>LM-SOP-QP-COC</b>
<b>Managing Non Conformances in the Q-Pulse CAPA Module</b>	<b>LM-SOP-QP-CAPA</b>

### 5.5.3

#### Documentation of Examination Procedures

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

Document References	Q-Pulse Reference
<b>Laboratory Procedure Document Template</b>	<b>LM-TEM-SOP</b>

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:

- a) purpose of the examination
- b) principle and method of the procedure used for examinations
- c) performance characteristics (see 5.5.1.2 and 5.5.1.3)
- d) type of sample (e.g. plasma, serum, urine)
- e) patient preparation
- f) type of container and additives
- g) required equipment and reagents
- h) environmental and safety controls
- i) calibration procedures (metrological traceability)
- j) procedural steps
- k) quality control procedures
- l) interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions
- m) principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values
- n) biological reference intervals or clinical decision values
- o) reportable interval of examination results
- p) instructions for determining quantitative results when a result is not within the measurement interval
- q) alert/critical values, where appropriate
- r) laboratory clinical interpretation
- s) potential sources of variation
- t) references

The active copy of an SOP can be viewed by all staff at any Trust networked computer in Laboratory Medicine via the WebViewer facility on Q-Pulse or Q-Pulse itself. An authorised hard copy is, (or copies are), available for reference at the location(s) of use. Hard copies authorised for use are stamped, 'AUTHORISED COPY'. 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](#)).

## 5.6 Ensuring Quality of Examination Results

### 5.6.1 General

Laboratory Medicine 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' – Laboratory Medicine 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
<a href="#">Clinical Biochemistry Quality Policy</a>	<a href="#">CB-POL-QA</a>
<a href="#">Microbiology Quality Policy</a>	<a href="#">MB-POL-QA</a>
<a href="#">Haematology Quality Policy</a>	<a href="#">HA-POL-QA</a>
<a href="#">Histology Quality Policy</a>	<a href="#">HI-POL-QUALITY</a>
<a href="#">Cytology Quality Policy</a>	<a href="#">CY-POL-QUALITY</a>
<a href="#">Point of Care Quality Policy</a>	<a href="#">PC-POL-QA</a>

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

Document References	Q-pulse Reference
<b>Management of Internal QC within Clinical Biochemistry</b>	<b>CB-SOP-IQC</b>
<b>Management of Internal QC within Haematology</b>	<b>HA-SOP-IQC</b>
<b>Microbiology: Internal Quality Assurance Procedure to Follow in the Event of QC Failure</b>	<b>MB-SOP-QC-IQA</b> <b>MB-SOP-QCFAIL</b>
<b>Histology Quality Policy</b>	<b>HI-POL-QUALITY</b>
<b>Management of Internal QC within Cytology</b>	<b>CY-SOP-IQC</b>

### 5.6.3 Interlaboratory Comparisons

#### 5.6.3.1 Participation

Each Laboratory Medicine department 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 External services and supplies](#)).

Document References	Q-Pulse Reference
<b>Clinical Biochemistry: Procedure for the Management of EQA</b>	<b>CB-SOP-EQA</b>
<b>Transfusion NEQAS Samples</b>	<b>BT-SOP-NEQAS</b>
<b>Haematology: External Quality Assurance Scheme Procedures</b>	<b>HA-SOP-EQA</b>
<b>Telepath EQA sample entry and on-line reporting</b>	<b>IM-SOP-EQA</b>
<b>Microbiology: Investigation of EQA Samples</b>	<b>MB-SOP-QC-EQA</b>
<b>Histology: Procedure for the Management of EQA</b>	<b>HI-SOP-NEQAS</b>
<b>Cytology: Procedure for the Management of EQA</b>	<b>CY-SOP-EQA</b>

### 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 a number of 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.
- Laboratory Medicine 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 preventative 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 Medicine Clinical Governance Meeting and included in the Annual Management Review ([see 4.11 Preventative action](#)), ([see 4.15 Management Review](#)).

## 5.6.4 Comparability of Examination Results

Laboratory Medicine 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](#)).

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
<a href="#">Procedure for ensuring comparability of Biochemistry results</a>	CB-SOP-COMPARE

<b>Comparability of Transfusion results between Scarborough and York</b>	<b>BT-SOP-COMPARE</b>
<b>Procedure for ensuring comparability of Haematology results</b>	<b>HA-SOP-COMPARE</b>
<b>Cross-Site Comparability of Examination Results</b>	<b>MB-SOP-COMPARE</b>
<b>Histology Quality Policy</b>	<b>HI-POL-QUALITY</b>
<b>Histology Proficiency Testing Policy</b>	<b>HI-POL-PT</b>

## 5.7 Post-examination Processes

### 5.7.1 Review of Results

Laboratory Medicine 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 Quality Control](#)) and, as appropriate, available clinical information and previous examination results ([see 4.7 Advisory services](#)). Procedures include:

Document References	Q-Pulse Reference
<b>Clinical Biochemistry: Technical Validation Processes</b>	<b>CB-SOP-TECHVAL</b>
<b>DEPHO Information Sheet - Scarborough &amp; York</b>	<b>CB-INF-DEPHO</b>

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

Laboratory Medicine has a documented policy to ensure compliance with this clause. The policy 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).

Document References	Q-Pulse Reference
<b>Policy for the Retention, Storage and Disposal of Laboratory Samples</b>	<b>LM-POL-RSDS</b>

## 5.8

## Reporting of Results

### 5.8.1 General

The documentation of departmental examination procedures ([see 5.5.3](#)) provides details of specific reporting requirements for each examination. Laboratory Medicine 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, maximizing accessibility and audit trail and reducing the potential for transcription errors. Test results are issued electronically to both Trust 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 Medicine 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 York Teaching Hospital NHS Foundation Trust 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
<a href="#">The Reporting of Laboratory Medicine Results</a>	<a href="#">LM-POL-RESULTS</a>
<a href="#">Notification to users of delays in reporting results from Biochemistry</a>	<a href="#">CB-SOP-DELAY</a>
<a href="#">Haematology: Amending, Delayed and Failed Reports</a>	<a href="#">HA-SOP-AMENDRPT</a>
<a href="#">Microbiology: Procedure for user notification of Laboratory Delay</a>	<a href="#">MB-SOP-TP-REPORT</a>
<a href="#">Histology: Consultant Reporting Procedure</a>	<a href="#">HI-SOP-CON REP</a>
<a href="#">Cytology: Turnaround Times</a>	<a href="#">CY-SOP-S-TRTIMES</a>

### 5.8.2 Report Attributes

Laboratory Medicine ensures that the report attributes effectively communicate laboratory results and meets the users' needs:

- 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.
- Comments regarding the sample suitability with respect to acceptance/rejection criteria are included to explain any non-reporting of results.
- 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.
- Interpretive comments on results, where applicable.

### 5.8.3 Report Content

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

- a) Identification of the examination, including where appropriate the examination procedure
- b) The identity of the Trust issuing the report, i.e. York Teaching Hospital NHS Foundation Trust. 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.
- c) Identification of any tests undertaken by a referral laboratory
- d) Patient identification and patient location on each page of the report.
- e) Identification of the requester and the requester's location
- f) Date of the primary sample and (where appropriate and relevant) the sample collection time.
- g) The type of primary sample received
- h) The measurement procedure utilised (if appropriate)
- i) Examination results reported in SI units, units traceable to SI units, or other applicable units.
- j) Biological reference intervals, clinical decision values (if appropriate)
- k) Result interpretation (if appropriate)
- l) Cautionary or explanatory notes as discussed in [5.8.2 Report Attributes](#)
- m) Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available
- n) 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)
- o) 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)
- p) 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:

- a) 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.
- b) 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?
- c) 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.
- d) When results are transmitted as an interim report, the final report is always forwarded to the requestor.
- e) 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.

Documented departmental procedures which consider the above and procedures for giving reports by telephone:

Document References	Q-Pulse Reference
Telephone Reporting and Requesting Procedure	BT-SOP-TEL
Automated Section - Processing Urgent & Phone Requests	CB-SOP-URGENTS
Giving results by telephone	SR-SOP-PHONE
Telephone Enquires	CY-SOP-P-PHONE
Urgent Haematology Samples	HA-SOP-URGENT
Telephone Enquiries	HO-SOP-PHONE
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:

- 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
- 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.
- The impact that sample interferences (e.g. haemolysis) may have upon the examination results.
- The process for incorporating analytical warning messages from instruments into the automated selection and reporting criteria.
- How results selected for automated reporting can be identified at the point of review, in advance of result release and include date and time of selection.
- 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 <i>describes the process for full blood counts</i> Coagulation Screen (ACL TOP) <i>includes an overview of autovalidation</i> Reviewing & Editing Patient Results <i>describes which results are presented for review</i>	HA-SOP-FBC  CO-SOP-COAGSCREEN  BT-SOP-EDIT
Microbiology: Automated Selection & Reporting of Results	The consultant team authorise all positive results where an individual clinical comment on interpretation or treatment might be of value. Other reports are released with a clinical auto-comment if they meet defined criteria. The remaining results are auto-authorised. See MB-SOP-TP-REPORT

Automated selection and reporting of results does 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:

- a) The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;
- b) 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.
- c) The revised record shows the time and date of the change and the name of the person responsible for the change;
- d) 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](#)).

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
Amending Authorised Cytology Results	CY-SOP-S-AMNDRPTS

## 5.10 Laboratory Information Management

### 5.10.1 General

Laboratory Medicine utilises the DXC (formally CSC & iSoft) i.Laboratory-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 with regard to patient information.

Laboratory Medicine 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 Laboratory Medicine:



- 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 S&N Department provides management of the systems with support of the Laboratory IT Systems Manager within the Laboratory Medicine Directorate itself. The Laboratory Medicine Impact Assessment [LM-INF-IMPACT] defines the processes involved and to an extent the authorities and responsibilities.

Directorate and Departmental 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:

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

### 5.10.3 Information System Management

The system used for the collection, processing, recording, reporting, storage or retrieval of

Document References	Q-Pulse Reference
<a href="#">Logging 'On' and 'Off' the Computer To Gain Access to Telepath</a>	LM-SOP-TP-LOGIN
<a href="#">Telepath Computer Daily Maintenance</a>	LM-SOP-TP-DMAINT
<a href="#">Telepath Computer Manager Duties</a>	LM-SOP-TP-MGR
<a href="#">Telepath Computer Fault Logging</a>	LM-SOP-TP-FAULTS

examination data and information is as previously

stated Telepath. Laboratory Medicine demonstrates compliance with ISO 15189:2012 a) – g) as follows:

a) Laboratory Medicine 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 VERTICAL AUDIT (Question 26).

b) Documented directorate and departmental procedures exist for the system which includes day to day functioning of the system ([see 5.10.2 Authorities and Responsibilities](#)). These are available within the Q-Pulse Document Module for all authorised staff.

Document References	Q-Pulse Reference
<b>Cytology: TELEPATH Verification (Document Module)</b>	<b>CY-VERI-LIMS</b>
<b>Microbiology: TELEPATH Verification (CAPA Module)</b>	<b>MB-VAL-LIMS</b>
<b>Microbiology: TELEPATH Verification – York (Document Module)</b>	<b>MB-VERI-TP1307</b>
<b>Microbiology: TELEPATH Verification - Scarborough (Document Module)</b>	<b>SMB-VERI-TP1405</b>
<b>Histology: TELEPATH Verification (Document Module)</b>	<b>HI-VERI-LIMS</b>
<b>Blood Sciences: TELEPATH Verification (CAPA Module)</b>	<b>BS-VAL-LIMS</b>
<b>Blood Transfusion: TELEPATH Verification (CAPA Module)</b>	<b>BT-VAL-LIMS</b>
<b>Blood Transfusion: TELEPATH Verification Prep (CAPA Module)</b>	<b>BT-VAL-LIMS PREP</b>

c) Security access to the system is strictly controlled via the Trust S & N 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](#)).

d) 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 Laboratory Medicine has a defined security policy which reinforces these requirements for laboratory staff ([see 4.1.1.3 Ethical Conduct](#)). 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.

e) Operational elements are undertaken by the Trust S & N Department who are responsible for the environment they are performed in.

f) System maintenance is undertaken by the Trust S & N Department. Electronic data is also backed up by the Trust's S & N 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 Maintenance and Repair](#)) and with the Laboratory Medicine IT Systems Manager.

g) 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.

Laboratory Medicine 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
<a href="#">Telepath Computer Fault Logging</a>	LM-SOP-TP-FAULTS
<a href="#">Microbiology Service Continuity Procedures</a>	MB-SOP-CONT PLAN
<a href="#">Histology Service Continuity Procedures</a>	HI-SOP-CONT PLAN
<a href="#">Cytology Service Continuity Procedures</a>	CY-SOP-SERVICE CONT
<a href="#">Mortuary Service Continuity Procedures</a>	MO-SOP-CONT PLAN
<a href="#">Clinical Biochemistry Service Continuity Procedures</a>	CB-SOP-CONT PLAN
<a href="#">Haematology Service Continuity Procedures</a>	HA-SOP-CONT PLAN
<a href="#">Blood Transfusion Service Continuity Procedures</a>	BT-SOP-CONT PLAN

## Appendix 1: Related Standards/sub-clauses and Regulatory Body

Section of Manual and ISO 15189 Clause	ISO 15189 UKAS Linked Clauses	Human Tissue Act (HTA)	GMP (MHRA)	Health and Social Care Act (CQC)
<b>4.0 Management Requirements</b>				
4.1. Organisation and Management Responsibility				
4.1.1. Organisation				
4.1.1.1. General				
4.1.1.2. Legal entity				
4.1.1.3. Ethical conduct		C1,C2, GQ6		
4.1.1.4. Laboratory director	4.5, 4.8, 4.14.3, 4.14.4			
4.1.2. Management responsibility				
4.1.2.1. Management commitment	4.1.2.2, 4.1.2.3, 4.1.2.4, 4.1.2.5, 4.1.2.6, 4.1.2.7,4.15, 5.1.6, 5.1, 5.2, 5.3, 5.4, 5.5, 5.7			E3, W1
4.1.2.2. Needs of users	4.4, 4.14.3	C2		E2, C1, C2,R3, R4, W4
4.1.2.3. Quality policy				W1
4.1.2.4. Quality objectives and planning	4.2			E1,R1,W5
4.1.2.5. Responsibility, authority and interrelationships				W2,W3
4.1.2.6. Communication	4.14.4			W3
4.1.2.7. Quality manager				

4.2. Quality management system		GQ1	Chapter 1	
4.2.1. General requirements				
4.2.2. Documentation requirement				
4.2.2.1. General	4.1.2.3, 4.1.2.4, 4.2.2.2, 4.13.			
4.2.2.2. Quality manual	4.1.2.3			
4.3. Document control	4.13	GQ1	Chapter 4	
4.4. Service agreements	5.4.2, 5.5,		Chapter 7	
4.4.1. Establishment of service agreements	5.5.1			
4.4.2. Review of service agreement				E2
4.5. Examination by referral laboratories			Chapter 7	
4.5.1. Selecting and evaluating referral laboratories and consultants				
4.5.2. Provision of examination results				
4.6. External services and supplies	5.3			
4.7. Advisory services	5.1.2, 5.1.6			
4.8. Resolution of complaints	4.14.3	GQ5	Chapter 8	R4, W4
4.9. Identification and control of non-conformities	4.10	GQ2, GQ5		S2, R4,W4,W5
4.10. Corrective action	4.13, 4.14.5			
4.11. Preventive action	4.13			
4.12. Continual improvement	4.14.5			
4.13. Control of records	5.9.3, 5.2.6, 5.10.3, 4.15	GQ4		
4.14. Evaluation and audit		GQ2	Chapter 9	
4.14.1. General	4.15, 4.10, 4.11, 4.12			

4.14.2. Periodic review of requests, and suitability of procedures and sample requirements				
4.14.3. Assessment of user feedback				E2, C1
4.14.4. Staff suggestions				
4.14.5. Internal audit	4.13, 4.10	GQ2		
4.14.6. Risk management		GQ6		S4, S5
4.14.7. Quality indicators	4.12			
4.14.8. Reviews by external organisations				
4.15. Management review			Chapter 1	W5
4.15.1. General				
4.15.2. Review input	4.14.2, 4.14.3, 4.14.4, 4.14.5, 4.14.6, 4.14.7, 4.14.8, 5.6.3, 4.8, 4.6, 4.9, 4.12, 4.10, 4.11			
4.15.3. Review activities				
4.15.4. Review output				
<b>5.0 Technical Requirements</b>				
5.1. Personnel		GQ3	Chapter 2	
5.1.1. General				
5.1.2. Personnel qualifications				
5.1.3. Job descriptions				
5.1.4. Personnel introduction to the organisational environment				
5.1.5. Training				
5.1.6. Competence assessment				
5.1.7. Review of staff performance				
5.1.8. Continuing education and professional development				

5.1.9. Personnel records				
5.2. Accommodation and environmental conditions		PFE1, PFE2,PFE3	Chapter 3	E3
5.2.1. General				
5.2.2. Laboratory and office facilities				
5.2.3. Storage facilities				
5.2.4. Staff facilities				
5.2.5. Patient sample collection facilities				
5.2.6. Facility maintenance and environmental conditions				
5.3. Laboratory equipment, reagents and consumables	4.6	PE3	Chapter 3, Annexe 15	E3
5.3.1. Equipment				
5.3.1.1. General				
5.3.1.2. Equipment acceptance testing	5.5.1			
5.3.1.3. Equipment instructions for use				
5.3.1.4. Equipment calibration and metrological traceability				
5.3.1.5. Equipment maintenance and repair	4.1			
5.3.1.6. Equipment adverse incident reporting				
5.3.1.7. Equipment records	4.13			
5.3.2. Reagents and consumables			Chapter 6	
5.3.2.1. General				
5.3.2.2. Reagents and consumables-reception and storage				
5.3.2.3. Reagents and consumables- acceptance testing				
5.3.2.4. Reagents and consumables- inventory management				
5.3.2.5. Reagents and consumables- instructions for use				
5.3.2.6. Reagents and consumables- adverse incident reporting				
5.3.2.7. Reagents and consumables- records				

5.4. Pre-examination processes				
5.4.1. General				
5.4.2. Information for patients and users				
5.4.3. Request for information				
5.4.4. Primary sample collection and handling				
5.4.4.1. General				
5.4.4.2. Instruction for pre-collection activities				
5.4.4.3. Instructions for collection activities				
5.4.5. Sample transportation		GQ2, GQ3		
5.4.6. Sample reception				
5.4.7. Pre-examination handling, preparation and storage				
5.5. Examination processes				
5.5.1. Selection, verification and validation of examination processes				
5.5.1.1. General				
5.5.1.2. Verification of examination procedures				
5.5.1.3. Validation of examination procedures				
5.5.1.4. Measurement uncertainty of measured quantity values				
5.5.2. Biological reference intervals or clinical decision values				
5.5.3. Documentation of examination procedures	5.5.1.2, 5.5.1.3			
5.6. Ensuring the quality of examination results			Chapter 6	
5.6.1. General	4.14.7, 5.4, 5.7, 5.8			
5.6.2. Quality control				
5.6.2.1. General				
5.6.2.2. Quality control materials				
5.6.2.3. Quality control data				

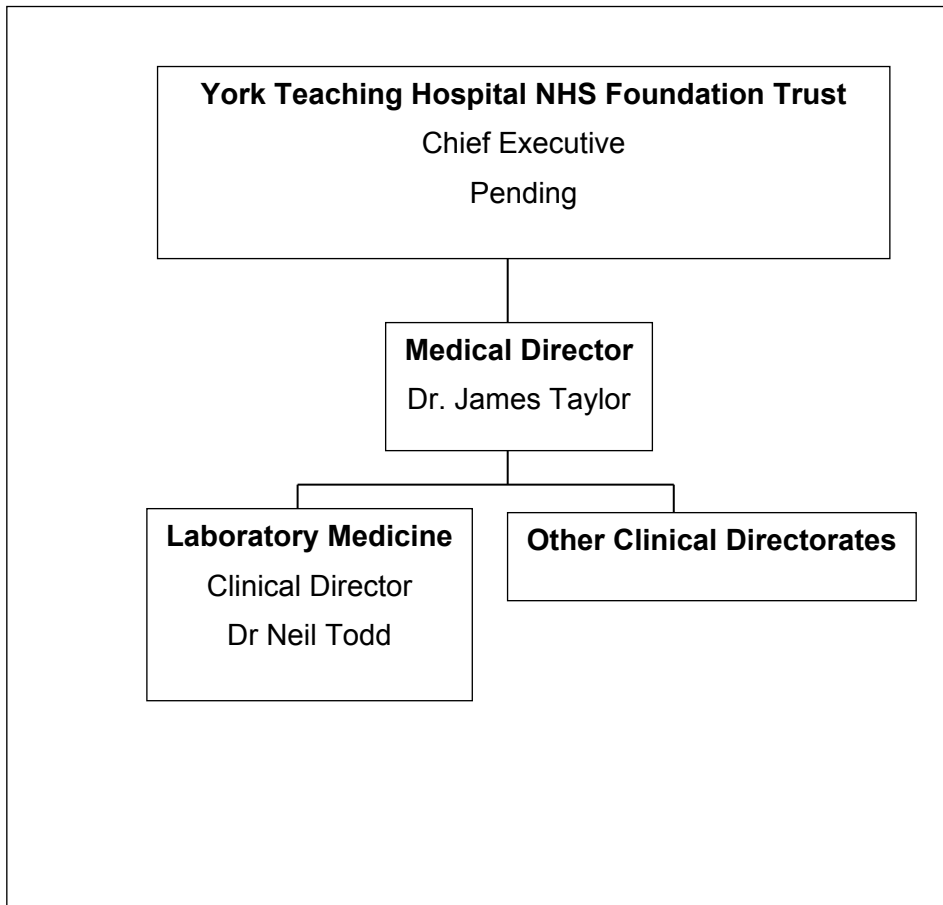


5.6.3. Interlaboratory comparisons				
5.6.3.1. Participation				
5.6.3.2. Alternative approaches				
5.6.3.3. Analysis of interlaboratory comparison samples				
5.6.3.4. Evaluation of laboratory performance				
5.6.4. Comparability of examination results				
5.7. Post- examination processes				
5.7.1. Review of results	5.9.2			
5.7.2. Storage, retention and disposal of clinical samples		T1,T2		
5.8. Reporting of results				
5.8.1. General				
5.8.2. Report attributes	5.9.2			
5.8.3. Report content				
5.9. Release of results				
5.9.1. General	4.5, 4.9			
5.9.2. Automated selection and reporting of results				
5.9.3. Revised reports				
5.10. Laboratory information management			Annexe 11	
5.10.1. General				
5.10.2. Authorities and responsibilities				
5.10.3. Information system management				

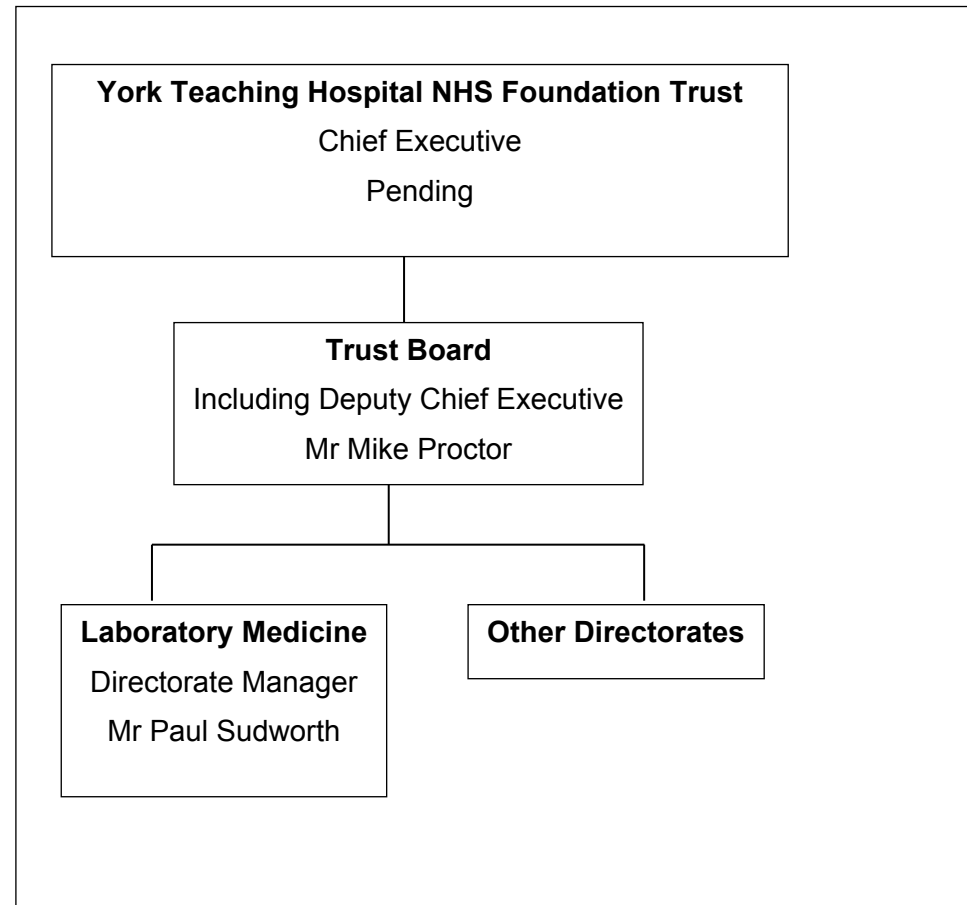
## Appendix 2: Organisation Charts

### Organisation Chart (1): York Teaching Hospital NHS Foundation Trust

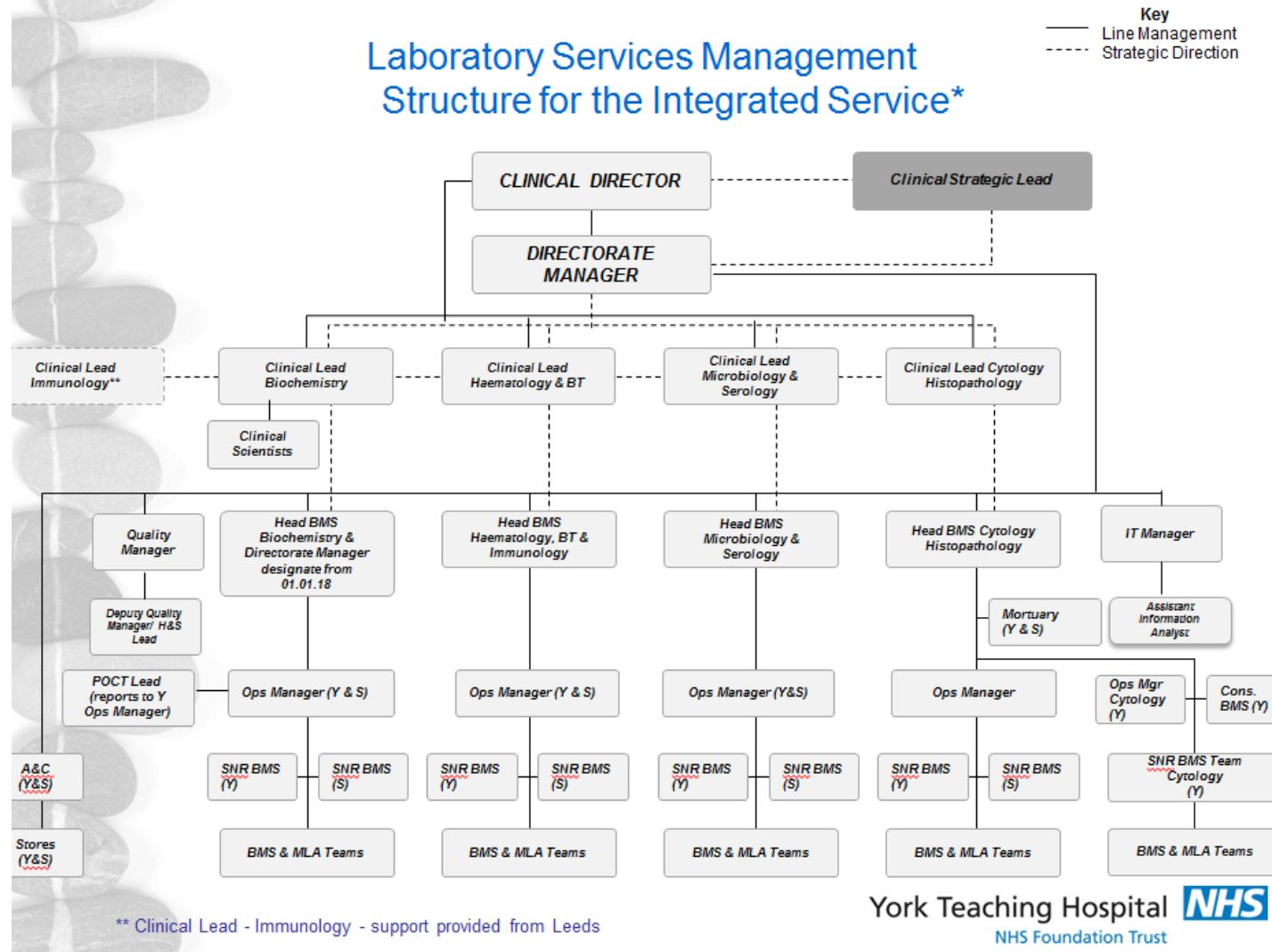
#### Clinical Responsibility



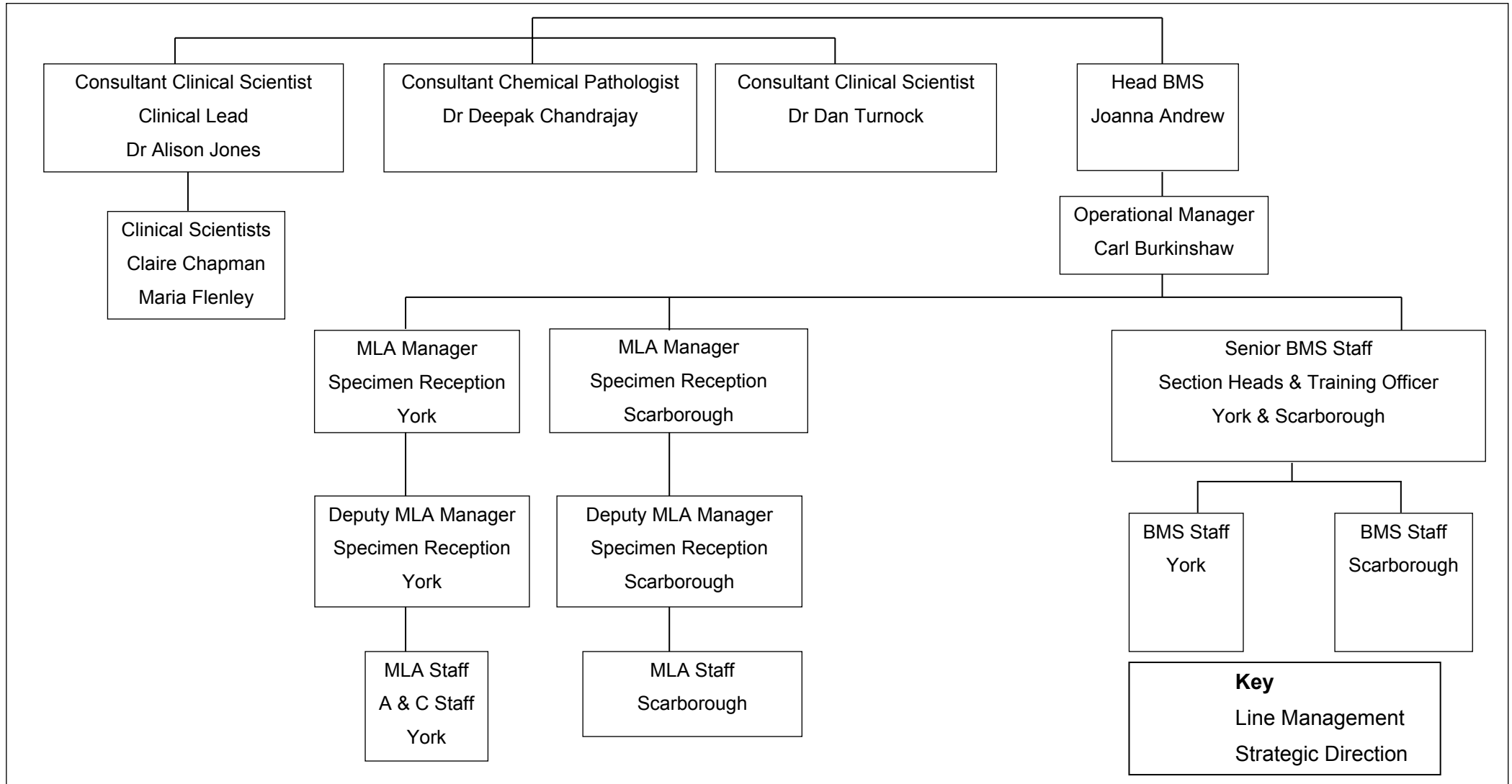
#### Operational Responsibility



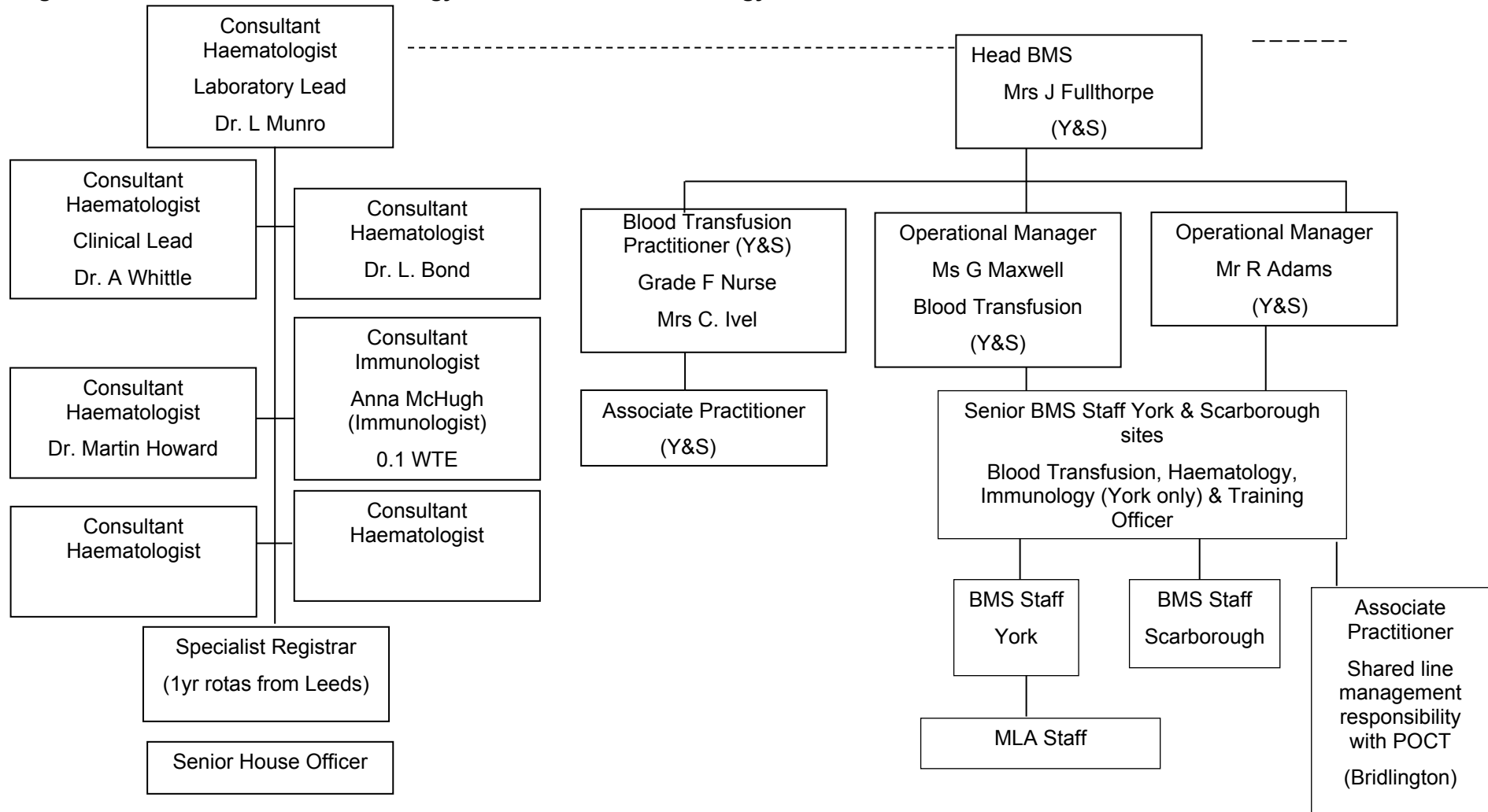
**Organisation Chart (2): Laboratory Medicine Management Structure for the Integrated Service**



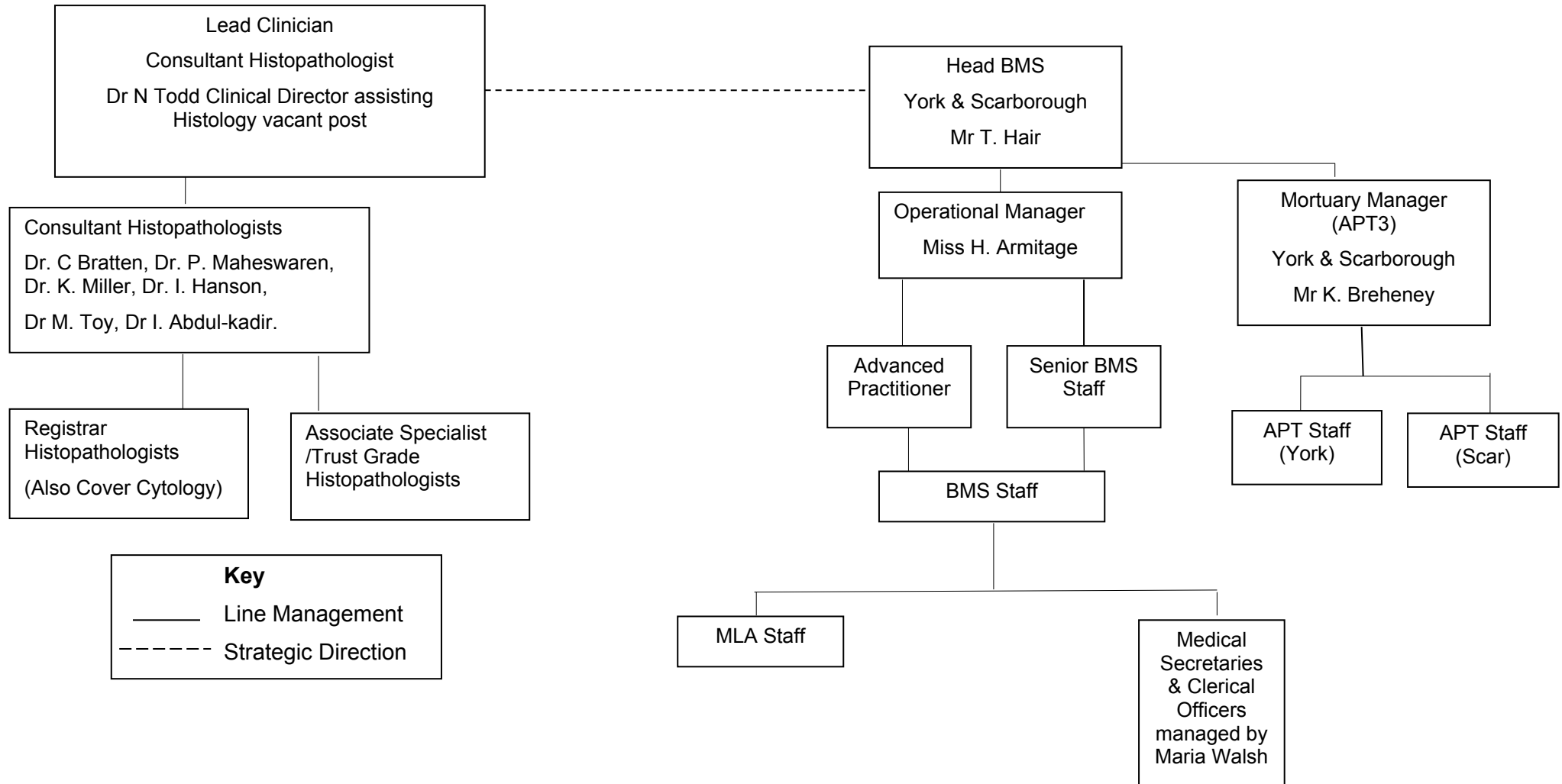
### Organisation Chart (3): York & Scarborough Clinical Biochemistry



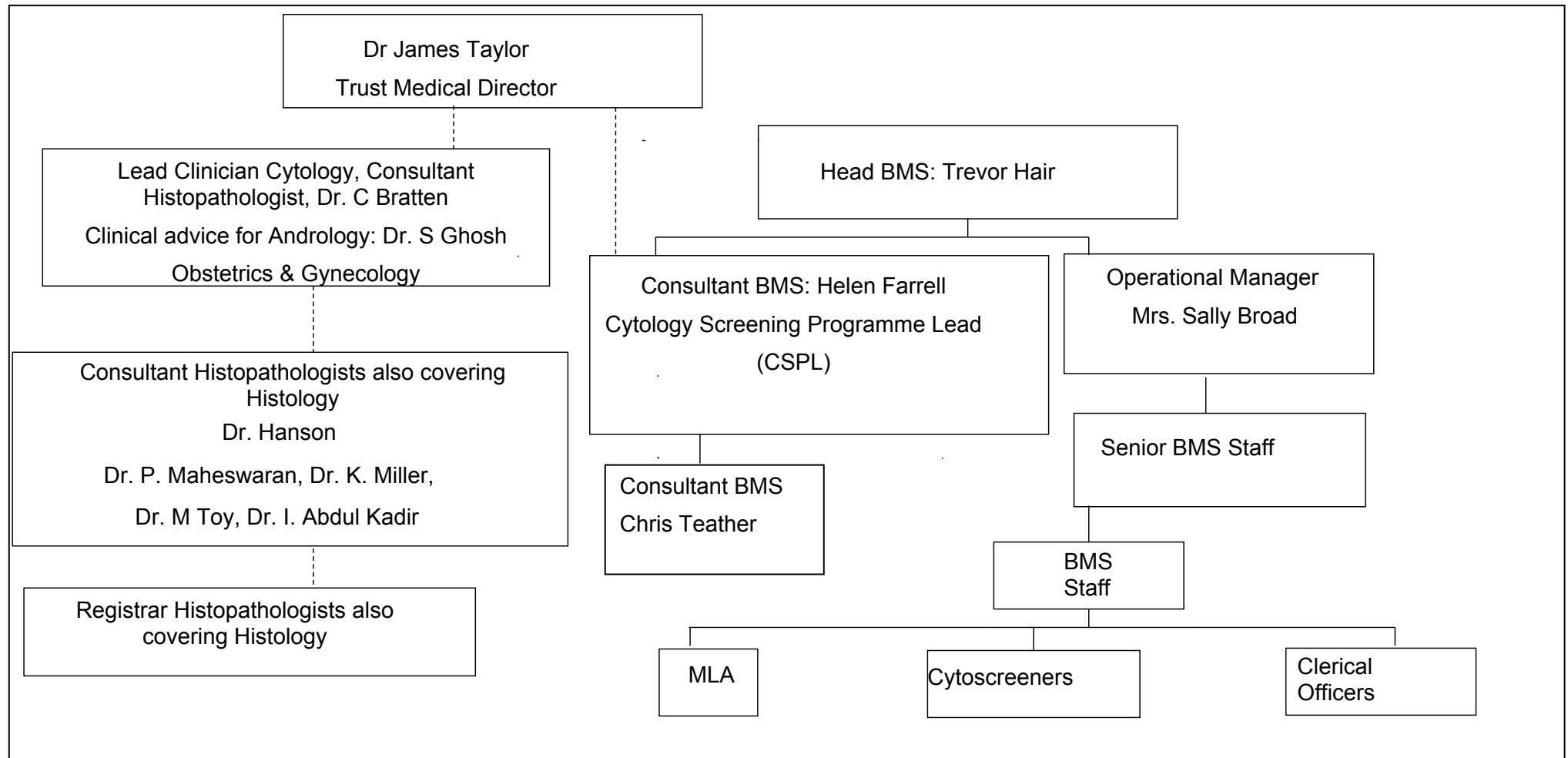
**Organisation Chart 4: York Haematology, Transfusion & Immunology**



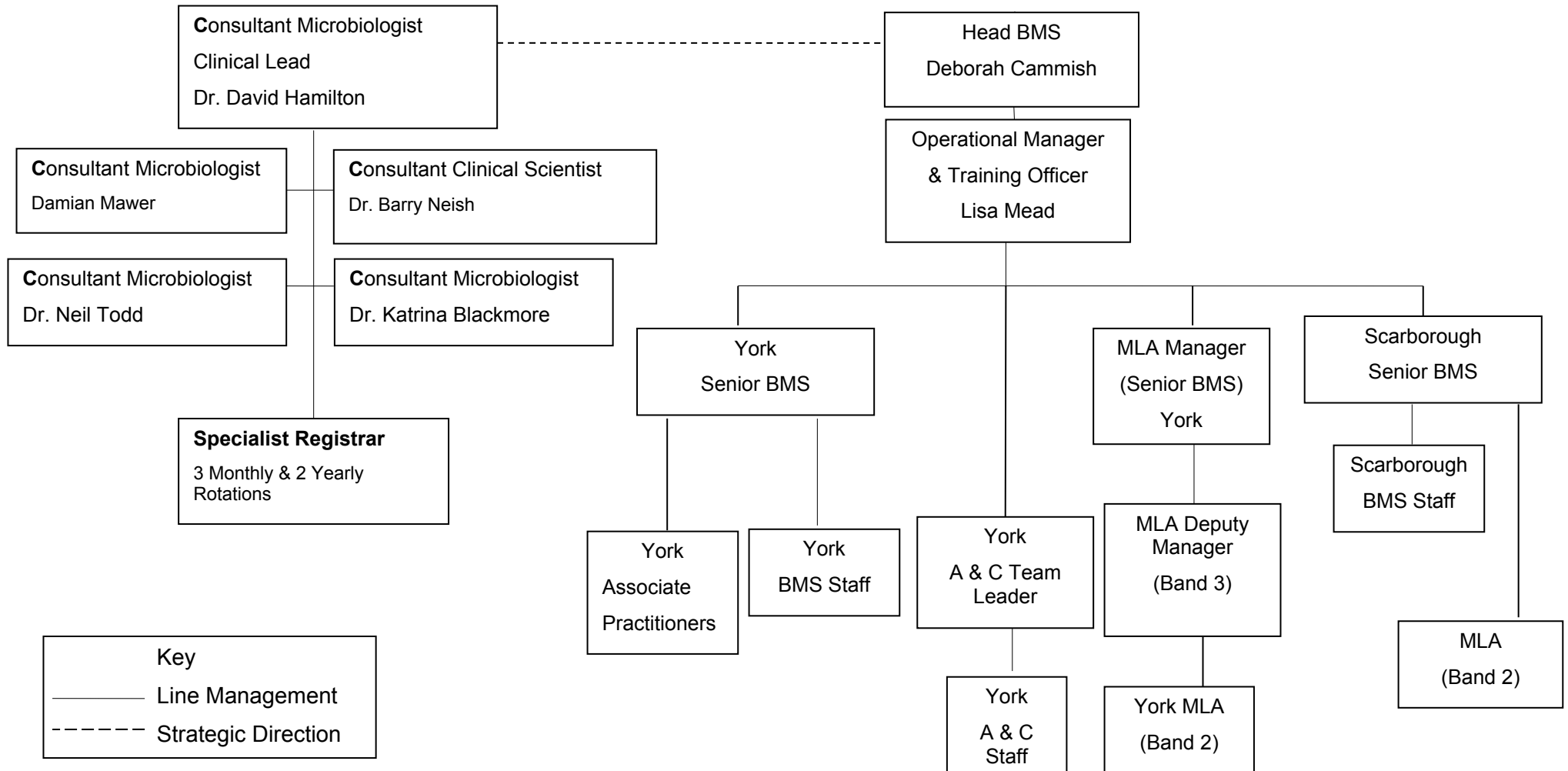
### Organisation Chart (5): York & Scarborough Histopathology



### Organisation Chart (6): North Yorkshire Cytology Screening Service

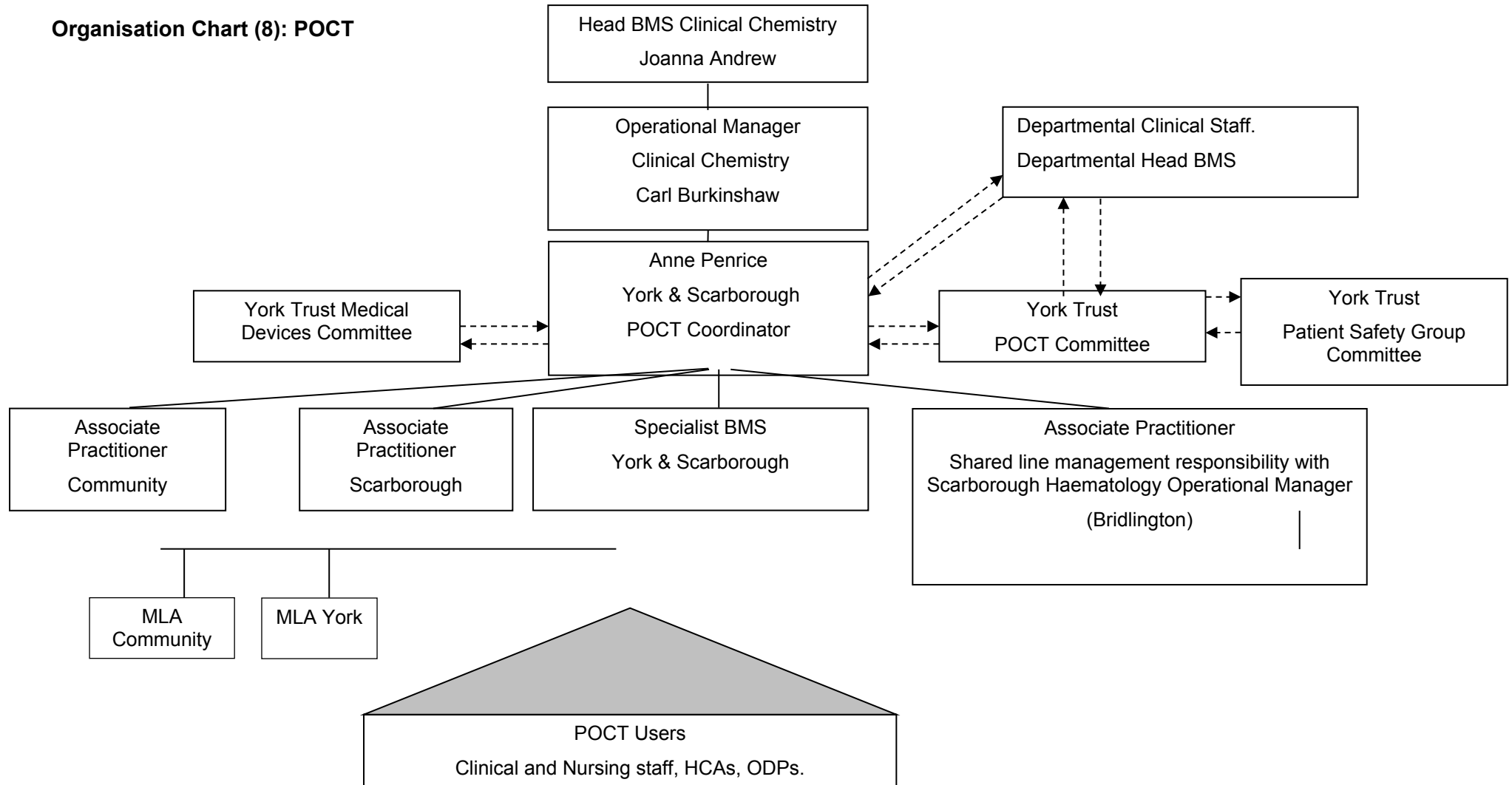


### Organisation Chart (7): Microbiology York & Scarborough

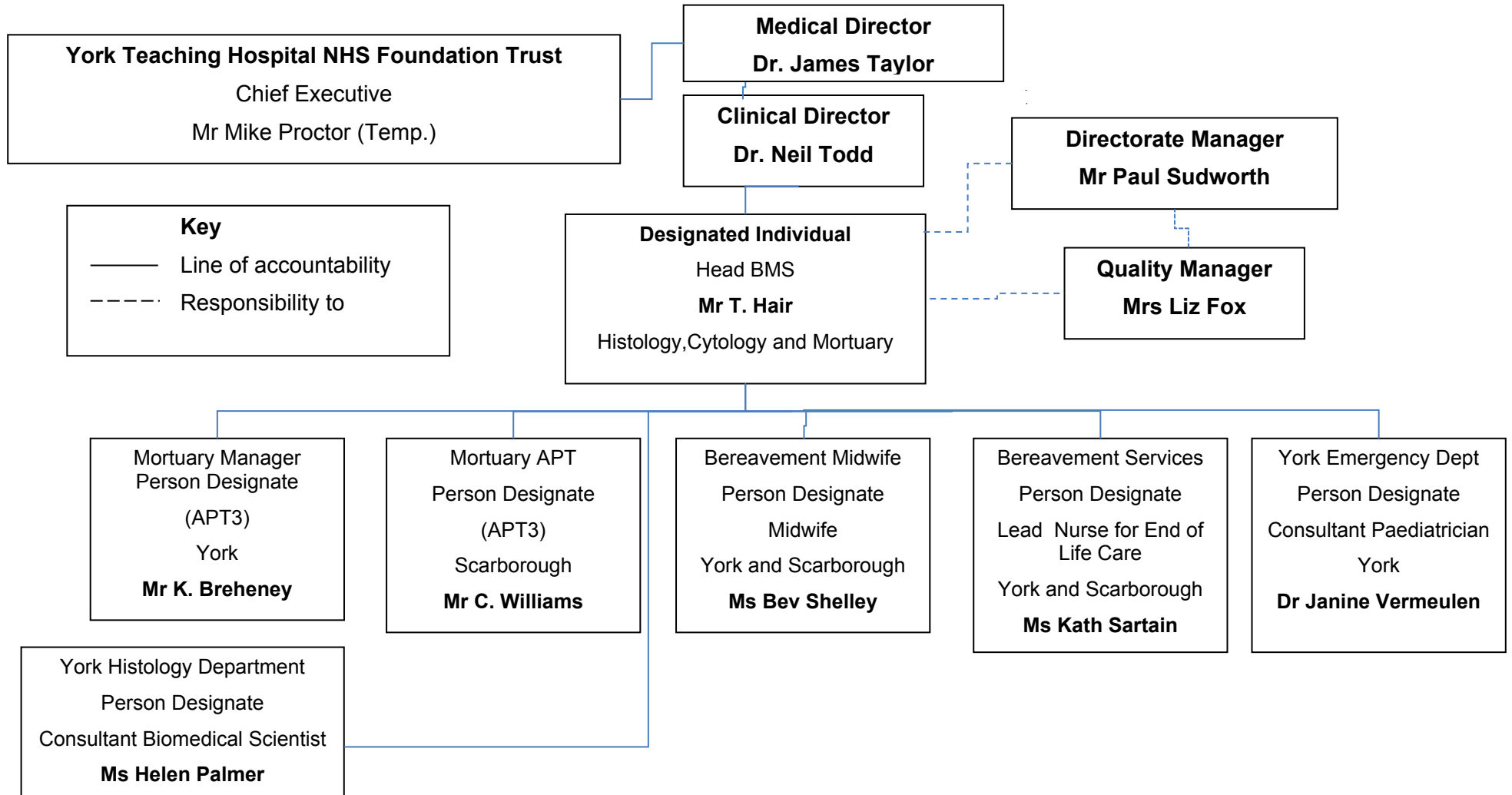




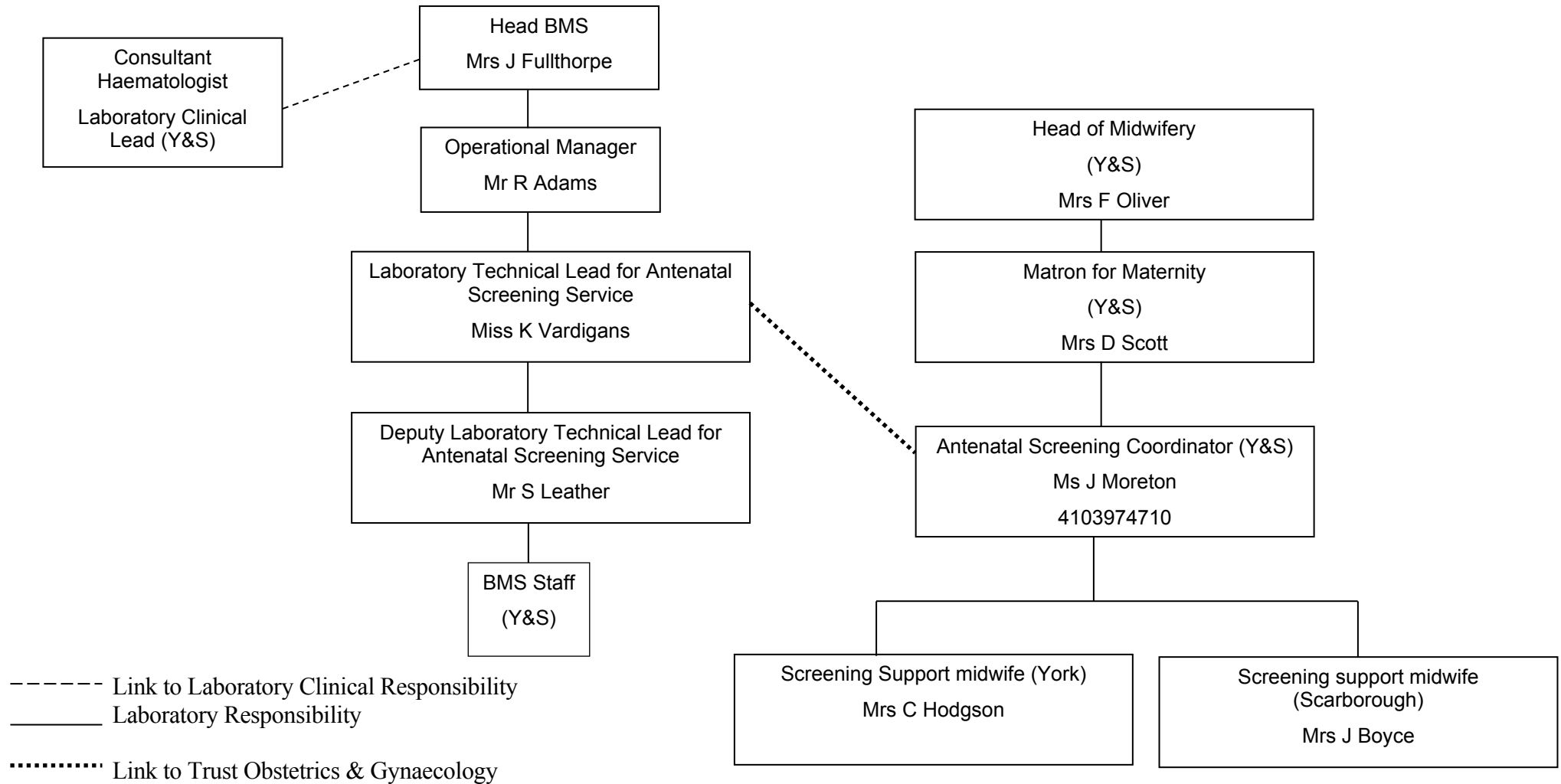
### Organisation Chart (8): POCT



**Organisation Chart (9): York Teaching Hospital NHS Foundation Trust: Human Tissue Authority – Roles and Responsibilities**



### Organisation Chart 10: Antenatal Screening Programme: Sickle Cell & Thalassaemia



## Appendix 3: Management Groups, Committees, and Meetings Schedules

Department	Title	Terms of Reference: Q-Pulse File Name	Minutes: Q-Pulse File Name		
Laboratory Medicine	Laboratory Medicine Directorate Management Team	LM-INF-TOR LMMT	LM-MIN-LMMT-YYMM		
Laboratory Medicine	Laboratory Medicine Clinical Governance Group	LM-INF-TOR CGOV	LM-MIN-CG-YYMM		
Laboratory Medicine	Laboratory Medicine Health & Safety Committee	LM-INF-TOR H&S	LM-MIN-H&SYMM		
Laboratory Medicine	Laboratory Medicine Transport Group	LM-INF-TOR TRAN	LM-MIN-TGYMM		
Laboratory Medicine	Scarborough Health & Safety Forum	SLM-INF-TOR H&S	SLM-MIN-H&SYMM		
Laboratory Medicine	Pathology CPD Group	LM-INF-TOR CPD	LM-MIN-CPDYMMDD		
Laboratory Medicine	Training Officers Group	LM-INF-TOR TRAINING	LM-MIN-TOYMMDD		
Laboratory Medicine	Laboratory Medicine Quality Forum	LM-INF-TOR QUALITY	LM-MIN-QUAL YYMM		
Laboratory Medicine	Blood Science Steering Group	LM-INF-TOR BSSG	LM-MIN- BSSGYMMDD		
POCT	POCT Committee	LM-INF-TOR POCT	PC-MIN-YYMMDD		
Department	Title	Remit	Membership	Frequency	Q-Pulse File Name
Laboratory Medicine	Admin Staff Meeting (York)	Updates	Admin Manager Secretarial Staff Delegated secretary	Alternate Months	LM-MIN-ADMINYYMM
Clinical Biochemistry					
Clinical Biochemistry	Senior Management Team	Strategy Operational Management	Clinical Lead Consultant Clinical Scientist (Chair) Head BMS Operational Manager	Monthly or less if insufficient attendees available	CB-MIN-SMTYYMM
Clinical Biochemistry	Assay & Quality	Assay Performance including EQA, IQC & TAT. Assay Justification Assay Development	Clinical Scientist (Chair) QA Officer Section Heads & co-opted members as required cross site.	Bi Monthly split between Automated and Immunoassay	CB-MIN-A&QCHEMYMM CB-MIN-A&QIMMYMM
Clinical Biochemistry	Senior Staff – York & Scarborough	Operational Management. Health & Safety. Quality Management Staffing	Head BMS (Chair) Operational Manager Section Heads	Nominally monthly but as required or if requested.	CB-MIN-SENYMMDD
Clinical Biochemistry	Staff Huddles	Information dissemination	Available staff	Daily York Weekly Scarborough	CB-MIN-DAILYHUDDLE YYMMDD SCB-MIN-WHUDYYMM
Clinical Biochemistry	Full Staff – York Full Staff - Scarborough	Information dissemination on:- Team Brief. Health & Safety QA Issues/Feedback	Consultant Clinical Scientist or Head BMS (Chair) All Staff (Including MLA rep) Secretary - Mrs C McSkeane or	Monthly	CB-MIN-FULYYMMDD SCB-MIN-FULYYMMDD

Clinical Biochemistry	MLA Staff – York	Information dissemination. Feedback.	Mrs C Vipurs MLA Manager (Chair) Deputy MLA Manager (Secretary)	As required	OC-MIN-MLA-YYMM
Clinical Biochemistry	Duty Biochemists	Clinical Matters	All Clinical Scientists	Monthly	CB-MIN-DBYYMMDD
<b>Blood Sciences</b>					
Scarborough Clinical Biochemistry & Haematology	Blood Sciences Full Staff Meeting	Information dissemination on:- Team Brief. Health & Safety QA Issues/Feedback	Head BMS (Chair) Operational Manager All Staff (Including MLA rep) Secretary - Mrs C Vipurs	Monthly	SBS-MIN-FUL-YYMM
York Blood Sciences Specimen Reception	Weekly Huddles Blood Sciences Specimen Reception York	Information dissemination	MLA Staff	Weekly as required	SR-MIN-WEEKLYHUDDLE YYMMDD
<b>North Yorkshire Cytology Screening Service</b>					
Cytology	Senior Management Team	Operational Management	Head BMS (Chair) Consultant BMS, Operational Manager Senior BMSs (Secretary)	Monthly	CY-MIN-SENYYYMM
Cytology	Full Staff	Operational-Management Quality Audit EQA H & S	Head BMS (Chair) Consultant BMS (Secretary) Lead Clinician All technical staff, Clerical Staff.	Monthly	CY-MIN-FULYYMM
Cytology	York Gynaecological CPC Meeting	Review Histology & Cytology slides and discuss implications for patient management	Consultant Histopathologist (Chair) Consultant BMS (Secretary) Lead Clinician All Cytology Senior Staff All Gynaecology team invited	Alternate Months	CY-MIN-CPCYYMMDD
Cytology	Harrogate Gynaecological MDT Meeting	Review Histology & Cytology slides and discuss implications for patient management	Dr. E. Millward (Chair) Head BMS Consultant BMS All Gynaecology team invited. Manager of Cancer Services (Secretary)	Alternate Months	CY-MIN-HMDYYMMDD
Cytology	Scarborough Colposcopy CPC Meeting	Review Histology & Cytology slides and discuss implications for patient management	Mrs Ramaswamy (Chair) Operational Manager All Gynaecology team invited. Manager of Cancer Services (Secretary)	Monthly	CY-MIN-SMDYYMMDD
Cytology	Friarage Gynaecological CPC Meeting	Review Histology & Cytology slides and discuss implications for patient management	Alison Roberts (Chair) Dr. K Prasad Consultant BMS Dr. Henderson Manager of Cancer Services (Secretary)	Alternate Months	CY-MIN-FMDYYMMDD

Cytology	Hull Gynaecological CPC Meeting	Review Histology & Cytology slides and discuss implications for patient management	Consultant gynaecologists (Chair) Consultant BMS Consultant Histopathologists Colposcopy secretary (Secretary)	Alternate Months	CY-MIN-HUYMMDD
Cytology	NLAG CPC Meeting	Review Histology & Cytology slides and discuss implications for patient management	Consultant BMS Consultant gynaecologists (as required)	Monthly	CY-MIN-NLGYMMDD
<b>Haematology, Blood Transfusion and Immunology</b>					
Haematology	Haematology Senior Management Team	Discuss all Haem issues. Develop strategy. Report to Directorate Management.	Lead Clinician (Chair & Secretary) Head BMS Operational Manager	Monthly	HA-MIN-SMTYYMM
Haematology	Haematology Senior Meeting	Operational Management. Health & Safety. Quality Management Staffing	Head BMS Operational Manager Section Heads	Monthly	HA-MIN-SEN-YMMM
Haematology	Full Staff – York Full Staff - Scarborough	Formal forum for cascading Information / decision making on Haematology issues	Head BMS (Chair & Secretary) All staff	Monthly	HA-MIN-STAFFYYMM SHA-MIN-STAFFYYMM
Blood Transfusion	Hospital Blood Transfusion Group Joint with Scarborough	Better Blood Transfusion (National Guidelines)	Lead Clinician (Chair) Blood Transfusion Practitioner (Secretary) Head BMS Operation Manager Senior BMS Blood Transfusion Representatives from:~ Paediatrics Surgery Practice Development Team Nuffield Health. Obs. & Gynae. Accident & Emergency Anaesthetics Orthopaedics Director of Nursing PCT Ramsey Health NHSBT Representative (Hospital Liaison Team Leeds). Director of Nursing Minutes go to Medical Director.	Quarterly	BT-MIN-HTCYMM
Blood Transfusion	Hospital Blood Transfusion Team	Better Blood Transfusion (National Guidelines)	Blood Transfusion Practitioner (Chair & Secretary)	Regularly	BT-MIN-HTTYMM

			Lead Clinician Head BMS Operational Manager Senior BMS Blood Transfusion Other ATP's Clinical Nurse Specialist for Haemophilia Other clinical reps as invited.		
Immunology	Immunology Staff	Operational Audit Analysis QC Clinical Issues	Senior BMS (Chair & Secretary) Anna McHugh Immunology Staff	Regularly	IM-MIN-FS-YYMMDD
<b>Histopathology</b>					
Histology	Full Staff Meeting	Team Brief. Information dissemination Feedback	Head BMS (Chair & Secretary) All Staff	Monthly	HI-MIN-FULYYMM
Histology	Senior BMS Staff	Operational Management Health & Safety Quality Management Staffing	Head BMS (Chair) Operational Manager Section Heads Designate (Secretary)	Nominally monthly but as required or if requested	HI-MIN-SBMSYYMM
Histology	Histology Consultant's Meeting	Information, dissemination, strategy Operational management	Lead Clinician (Chair & Secretary) All Histology Consultants	Monthly	HI-MIN-CONSYMMDD
<b>Microbiology</b>					
Microbiology	Senior Management Team Joint with Scarborough (Routine Microbiology & Serology)	Progress reports re: staffing, Training, technical developments. Audit	Lead Clinician (Chair) Consultant Microbiologists Head BMS Operational Manager Senior BMS Medical Secretary (Secretary)	Monthly	MB-MIN-SM-YYMMDD
Microbiology	Clinical Governance Meeting Joint with Scarborough	Clinical Governance	Clinical Lead Clinical Staff Head BMS (Chair) Operational Manager Senior BMSs H & S Representative Medical Secretary (Secretary)	Alternate Months	MB-MIN-CGYMMDD
Microbiology	Senior BMS Staff Joint with Scarborough	Progress reports re: staffing, Training, technical developments.	Head BMS (Chair) Operational Manager Senior BMSs Designate (Secretary)	Monthly	MB-MIN-SN-YYMMDD
Microbiology	Audit Meeting (commenced February 2015) Joint with Scarborough	Audit presentations both Clinical & Laboratory based and to review any difficult to	Senior BMS (Chair & Secretary) All BMS& support staff as appropriate and available.	Bi-Monthly	MB-MIN-AUDITYMMDD

		resolve CAPAs.			
Microbiology	Full Staff Meeting – York Full Staff Meeting - Scarborough	Operational issues, training, updates, team brief.	Head BMS (Chair) All Staff Designate (Secretary)	Bi-Monthly Monthly	MB-MIN-FULYYMMDD SMB-MIN-FULYYMMDD
Microbiology	Start Up Meeting – York only	Operational issues	Senior BMS (Chair & Secretary) All BMS & support staff as appropriate and available.	Weekly	MB-MIN-SUYYYMMDD
Microbiology	Morning Huddle – Scarborough only	Operational issues	Senior BMS (Chair & Secretary) All BMS & support staff as appropriate and available.	Weekly as appropriate	SMB-MIN-HUDYYMMDD
Microbiology	BMSs – York only	BMS operational issues Service improvement	Head BMS (Chair) All BMS Staff Designate (Secretary)	Quarterly (or less if no issues)	MB-MIN-BMSYYMMDD
Microbiology	Associate Practitioners – York only	AP operational issues Service improvement		Quarterly	MB-MIN-APYYMMDD
Microbiology	MLA's – York only	MLA operational issues Service improvement	Head BMS (Chair) Operational Manager All MLA staff Designate (Secretary)	Quarterly	MB-MIN-MLAYYYMMDD
<b>Mortuary</b>					
Mortuary	Full Staff Meeting – York & Scarborough	Operational issues, training, updates, team brief, H&S.	Head BMS (Chair & Secretary) Clinical Lead Mortuary Manager APTs Quality Manager Bereavement Services Rep	Monthly	MO-MIN-FULYYMM