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"First Choice for Patients"

Dartford and Gravesham NHS
NHS Trust

CONTROLLED DOCUMENT

Pathology Directorate Quality Manual.

INDEX	Pathology - 3886
VERSION No	1.9
DOCUMENT TYPE	Management
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AUTHORISED BY	Emma Clenshaw
AUTHORISATION DATE	30-Apr-2013
REVIEW DATE	30-Apr-2015
DATE PRINTED	12-Jun-2013 10:04
LOCATION OF COPY	Mortuary Suite ~ All areas
COPY	1

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Introduction and Scope

This document together with specified procedure manuals represents the Quality Management System of the Pathology Directorate, Dartford and Gravesham NHS Trust. It has been compiled to meet the requirements of Clinical Accreditation [UK] Ltd. [CPA]. The Human Tissue Authority [HTA] and the Blood Safety and Quality Regulations [BSQR] As all departments within Darent Valley Pathology Directorate operate within the same Quality Management System [QMS] this Quality Manual is common to all departments.

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Pathology Directorate

Quality Manual

Dartford and Gravesham NHS Trust

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1. General Information.

Dartford and Gravesham NHS Trust provide a comprehensive range of acute health services for the residents of Dartford, Gravesham and Swanley. The Trust Headquarters are based at Darent Valley Hospital, Level 4.

Darent Valley Hospital is a Private Finance Initiative [PFI] Hospital. It has around 476 inpatient beds providing inpatient and outpatient care for around 270,000 people in Dartford, Gravesham, Swanley and Bexley. Opened in 2000, Darent Valley replaced three old and outdated hospitals, Joyce Green and West Hill hospitals in Dartford and Gravesend and North Kent Hospital in Gravesend.

2. The Pathology Directorate.

The Pathology Directorate is located on Level 3, East Wing at Darent Valley Hospital. All departments are located at Darent Valley Hospital.

Postal Address is:	Pathology Directorate,	Tel.	01322 428491	General Enquiries
	Darent Valley Hospital,	Fax	01322 428493	
	Darenth Wood Road,			
	Dartford, Kent.			
	DA2 8DA			

There are three main disciplines within the Pathology Directorate providing routine services across the Trust, West Kent PCT, The Lions Hospice and Kings Renal Unit.

The Blood Science Sample Reception area sorts samples, on their arrival in the laboratory, into the appropriate disciplines. Microbiology and Blood Transfusion samples are redirected to the relevant laboratories. The staff within the Blood Science Sample Reception area bar code label and rack the samples for Haematology and Biochemistry analysis. This area together with the Phlebotomy Department is managed by the Laboratory Support Services Manager who is managerially responsible to the Pathology General Manager. Technical support and expertise is provided by the Haematology Laboratory Manager.

2.1 Haematology and Blood Transfusion:

Haematology encompasses a range of areas involved in the study of blood. Various types of blood cells are enumerated by automated techniques followed by staining and light microscopy when indicated. Coagulation screening is performed using automated analysers, as well the monitoring of anticoagulant therapy. Other investigations include investigation of suspected malaria infection, haematinic assay (reporting), and flow cytometric analysis of lymphocyte subpopulations as well as determination of HLA B27 phenotype. The Haematology laboratory also carries out Ante Natal Haemoglobinopathy screening

The Blood Transfusion Laboratory, by means of fully automated Blood Grouping analysers, performs routine blood grouping, antibody screening and identification both for the provision of safe blood and blood products and as part of the Ante-Natal Screening program.

The Blood Transfusion laboratory is subject to MHRA inspection under the Blood Safety and Quality Regulations [SI 2005/50].

2.2 Chemical Pathology

The Chemical Pathology Department is fully accredited by CPA [UK] Ltd.

The services provided by the two sections within the Biochemistry department are briefly described below:

Automated Section:

This section deals with the bulk of the tests performed by the Chemical Pathology department. Tests such as serum Renal and Liver and Bone profiles, Cholesterol etc are carried out in a large open area of the laboratory on two main Olympus AU640 analysers with their associated computer interfaces, printer, preparation areas and necessary consumables including an Elga Medica 100 for reverse osmosis water. Also within this area are two floor standing, high throughput Bayer Advia Centaur Immunochemistry analysers that perform thyroid, infertility, tumour markers, haematinics, troponin, digoxin and antibiotic assays.

Miscellaneous Section:

This section is responsible for the remainder of the Chemical Pathology workload and comprises a broad variety of techniques and assays, both manual and automated. The range of tests includes Protein Electrophoresis, High Performance Liquid Chromatography [HPLC] as well as spectrophotometric analyses through to sweat tests.

The Chemical Pathology Laboratory undertakes bile acid analysis for a neighbouring Trust.

2.3 Microbiology:

The Microbiology Department is fully accredited by CPA [UK] Ltd.

The services provided by the two sections within the Microbiology department are briefly described below:

General Microbiology:

This section of the laboratory is concerned with the isolation of medically significant bacteria, fungi and parasites. The laboratory carries out microscopy and culture investigations on urine, faeces, swabs from body sites and orifices, sputum, cerebro-spinal fluid, skin, hair, nails and blood. This section also performs investigations for the detection of Acid-Fast Bacilli and antibiotic assays against a range of organisms.

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Serology Section:

This section of the laboratory deals with Ante-Natal screening according to Government Guidelines and serological testing for a range of antigens and antibodies including HIV, Hepatitis (A, B, and C), CMV, Toxoplasma and Varicella. The laboratory also performs Chlamydia antigen testing, Clostridium difficile toxin testing. Investigations for Rotovirus and Legionella antigen are also carried out. Recent innovations include the processing of viral loads for HIV patients from the Department of Genito-Urinary Medicine.

The General Serology Section is the Referral Centre for West Kent for Interferon Gamma Release Assays (LTBI – Latent TB Infection)

Mortuary Services:

The Mortuary at Darent Valley is licensed by The Human Tissue Authority to perform Post Mortems

The Pathology Directorate provides Mortuary services to Kent County Council for Coroners' Post Mortems. These are carried out by a visiting Coroner's Pathologist.

Hospital Post Mortems are not undertaken.

Further information and a full description of the services provided are available in the Departmental Users Handbooks, copies of which are located on Darent Valley Hospital internet site www.dvh.nhs.uk and the Trust intranet site ~ Adagio.

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3. The Quality Manual.

This Quality Manual describes the Quality Management System of the Pathology Directorate. Throughout the text there are references to CPA [UK] Ltd Standards [in square brackets] and to Policies and Procedures [in square brackets], written in fulfillment of these Standards.

This Quality Manual [A6] fulfils two functions:

- It describes the Quality Management System for the benefit of the Laboratory's own management and staff [A6.2b]
- It provides information for users and for accreditation and inspection bodies.

The Quality Manual can be regarded as the index volume to separate manuals of management, laboratory, clinical and quality procedures.

The sections of the Quality Manual are arranged so that they equate with CPA [UK] Ltd. Standards ~

Section of Quality Manual		Section of CPA [UK] Ltd Standards
6	A.	Organisation and Quality Management System
7	B.	Personnel.
8	C.	Premises and Environment.
9	D	Equipment, Materials and Reagents.
10	E.	Pre-Examination Process.
11	F.	Examination Process.
12	G.	Post Examination Process.
13	H.	Quality Assurance and Evaluation.

Under the title of each Standard is a brief description of the way in which the Pathology Directorate seeks to comply with the particular Standard and references are given to appropriate procedures.

The sections of the Standards relate to each other in the following manner:

[Section A] describes the organisation of the laboratory and its Quality Management System, which uses resources [Sections B, C and D] to undertake pre-examination, examination and post examination processes [Sections E, F and G].

The Quality Management System and the examination processes are continually evaluated and Quality Assured [Section H]. The results feed back to maintain and improve the Quality Management process as required and to ensure that the needs and requirements of the users are met

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4. Pathology Directorate - Quality Policy.

The scope of service provided by the Pathology Directorate is that of an in house routine diagnostic service for Haematology, Blood Transfusion, Biochemistry, Microbiology – supplemented by a 24 hour out of hours' service, and Cellular Pathology – Histology and Cytology and Mortuary. The mortuary provides Post Mortem facilities for the Coroner.

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

In order to ensure this the Directorate will:

- Operate a Quality Management System to integrate the organisation, procedures, processes and resources. [A4]
- Set Quality Objectives and plans to implement this Quality Policy.[A5]
- Ensure that all personnel are familiar with the Directorate Quality Manual and all procedures relevant to their work by providing an acknowledge sheet that must be signed as read and understood by each member of staff relevant to that procedure.[A3.1c]
- Commit to the health, safety and welfare of all its' staff. [C5]
- Ensure that visitors to the Directorate will be treated with respect and due consideration will be given to their safety when on site.[C3 and C5]
- Uphold professional values and be committed to good professional practice and conduct. [A3.1e]
- Commit to comply with all relevant environmental legislation as appropriate to processes and procedures.
- Commit to confidentiality in accordance with the Data Protection Act and Caldicott Principles.

The Pathology Directorate will comply with the Standards set by CPA (UK) Ltd. The Blood Safety and Quality Regulations and The Human Tissue Authority and is committed to;

- Staff recruitment, training, development and retention at all levels to provide a full and effective service for all its users. [B2,B7,B9]
- The proper procurement and maintenance of such equipment and resources as are required for the provision of the service. [D1]
- The collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations. [E3]
- The use of examination procedures that will ensure the highest achievable quality of all tests performed. [F2]
- Reporting results of examinations in ways that are timely, confidential, accurate and clinically useful. [G1]
- The assessment of user satisfaction, [H2], in addition to Internal Audit [H3 and H4], External Quality Assessments, [H5], benchmarking and identification and control of non-conformities [H7] in order to produce continual Quality Improvement. [H6]

Signed by the Pathology Directorate Clinical Director **Date**

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5. Planning, Maintaining and Achieving Quality Objectives

Introduction

As part of a commitment to quality improvement including continuous compliance with Standards for the Medical Laboratory as published by CPA [UK] Ltd, Pathology management has established these procedures to define, achieve and maintain quality objectives. This includes recording the achievement of defined objectives and monitoring continuing objectives or progress towards achievement.

Quality Objective Planning

Quality objective planning is an annual activity timed around the Annual Management Review. Objectives are set and agreed by individual laboratory managers in partnership with the Quality Manager. Pan-Pathology quality objectives are set by the Senior Management Team with the Pathology Services Manager and agreed with the Quality Coordinator and Laboratory Managers.

Formal planning is based on follow up of the previous year's objectives, host organisation plans and requirements, clinical and scientific elements, staffing elements, accreditation and legislative requirements and elements identified within specific areas. Quality objectives may need to be redefined or added to throughout the year as a result of incident reports, complaints, and departmental developments and for various other reasons.

Key Quality Indicators

Additionally, each department has a set of defined key quality indicators which identify aspects of service measurement that are critical in defining service delivery and achievement of stated parameters. These should also be discussed at departmental laboratory meetings and findings from periodic measurements recorded.

Records

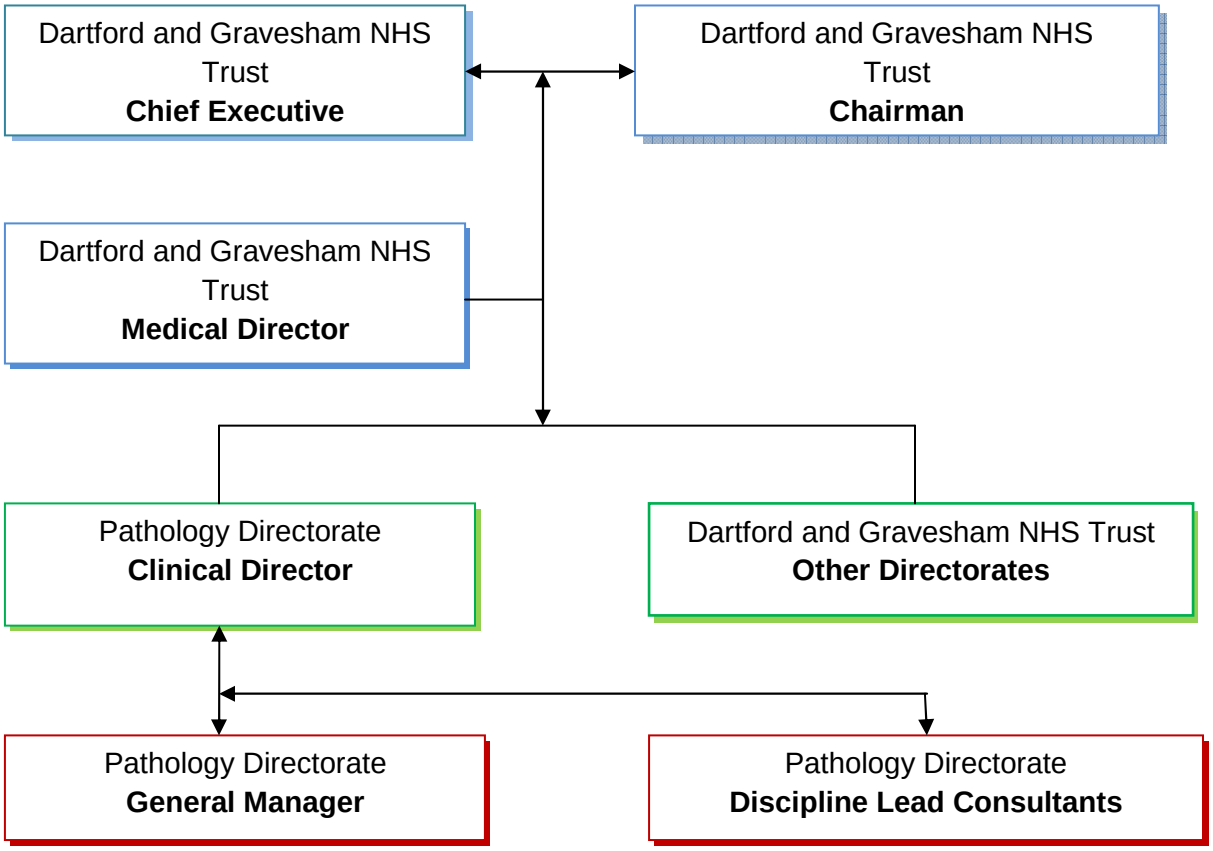
Quality objectives are formally recorded once defined and reviewed at the relevant departmental laboratory meetings and management appraisals.

Achievement and Maintenance of Objectives

Achievement of objectives is recorded at the Pathology Quality Management Group meetings as are any deviation from the quality level achieved. Plans to deal with deviations are then agreed and acted upon within a defined time frame by defined individuals. Achievement and maintenance of quality objectives forms part of the personal objectives for laboratory managers, the Quality Coordinator and departmental Quality Representatives.

6. ORGANISATION, RESPONSIBILITIES AND AUTHORITIES.

Relationship to the Host Organisation [A1.4]



The Pathology Directorate is also associated with the following external organisations:

- Clinical Pathology Accreditation [UK] Ltd. [CPA] UK. Ltd.
- Medicines and Healthcare Products Regulatory Agency. [MHRA]
- Human Tissue Authority. [HTA]
- National Blood Service. [NBS]
- Blood Safety and Quality Regulations. [BSQR]
- United Kingdom National External Quality Assessment Service. [NEQAS]
- HM Coroner.
- Kent County Council.
- NHS Cervical Screening Program External Quality Assurance Scheme.
- Kent Cancer Network
- West Kent and other Primary Care Trusts
- Kent and Medway Pathology Network

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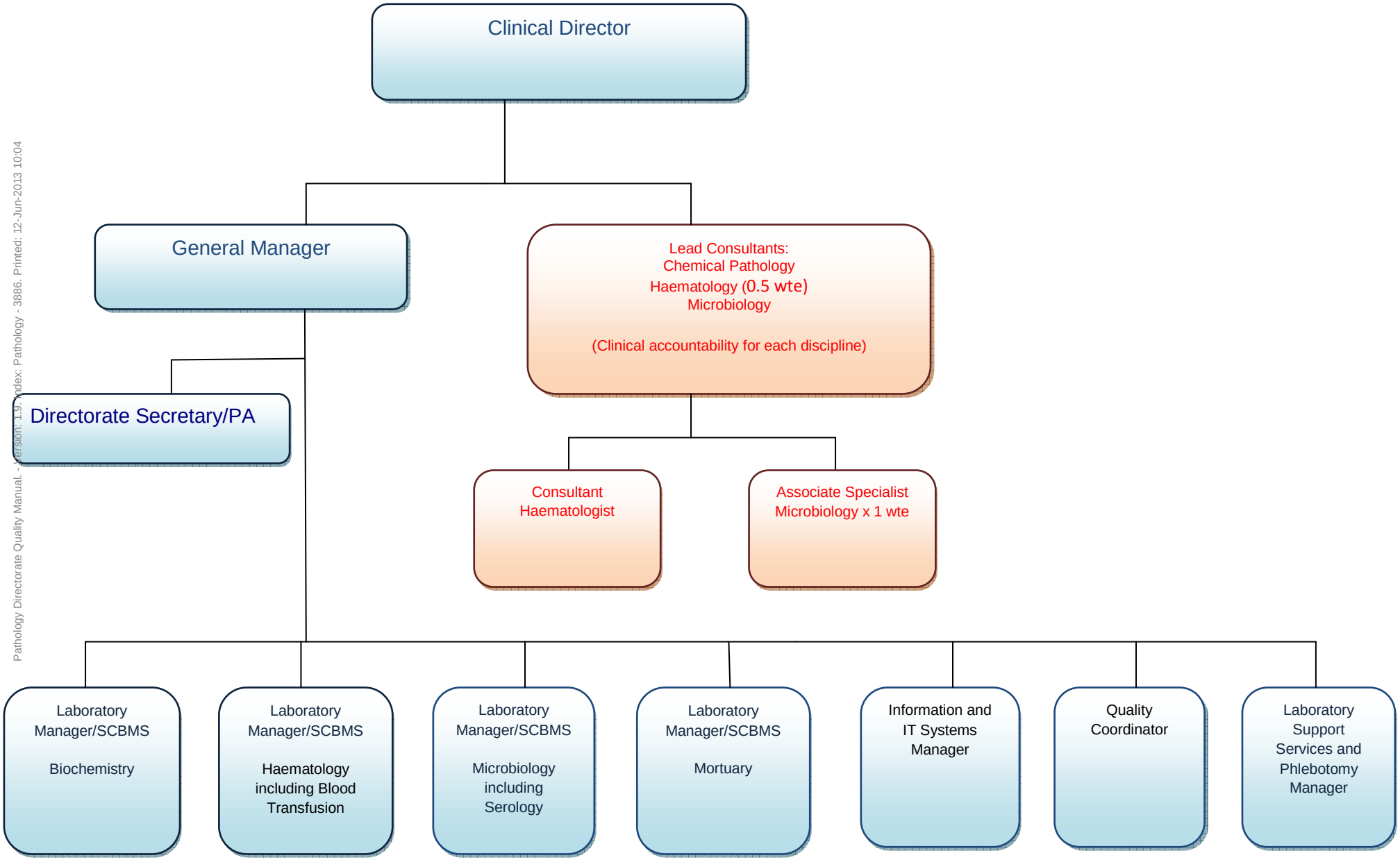
Pathology Directorate

Organisational and Management Structure [A1.4]

Key: Clinical Team
Operational and Management Team



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Clinical Director [B.1]

The Clinical Director is responsible and accountable for the performance of the Pathology Directorate. The Clinical Director manages the medical staff of the Directorate, ensuring that Quality and other Governance targets are met, and future plans for the service provision and development accord with evidence as to best and most cost-effective practice. The Clinical Director forms part of a group of senior medical staff providing co-ordination of medical services and communication with medical colleagues in primary care and elsewhere. They share responsibility for specific clinical services and play an instrumental role in identifying and securing resources necessary for delivering agreed service levels and future plans.

Key roles and responsibilities:
[Pathology Document 3914 ~ Delegation of Clinical Director Responsibilities]

- Strategic, Directorate and individual influencing, supporting, motivating and empowering others to lead.
- Influencing the standards for better health at Directorate level:
  - Ensuring processes are in place for monitoring and improving quality.
  - Contribution to delivering Healthcare Standards.
  - Setting priorities and developing innovation.
  - Addressing key issues and challenges.
  - Performance management of clinical staff and General Manager.
  - Contribution to clinical and organizational quality and performance measures
  - Budget holder (devolved to General Manager),
  - Risk and improving patient safety.
  - Ensuring patient safety is a top priority in the Directorate.
  - Ensuring Directorate Risk Assessment is undertaken by clinicians as appropriate and that clinicians report incidents linking patient safety measures to improved patient outcomes.
  - Managing performance and supporting doctors in difficulty.
  - Effective Consultant and team job planning.
  - Co-ordinate job planning across the team.
  - Appraising the Directorate Consultants.
  - Tackling performance issues that may arise within the appraisal.

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Clinical Leads.
The Clinical Leads are accountable to the Directorate Clinical Director. They provide clinical direction for each department and are available for clinical advice for users.

Directorate General Manager.
The Directorate General Manager has responsibility for service delivery and financial balance as well as the operational management and modernisation of Pathology Services within the Trust. The Directorate General Manager works with the Clinical Director and Laboratory/Operational Managers in liaison with the clinical team Leads to develop and implement the planning and performance management agenda for Pathology.

The Directorate General Manager provides management and operational leadership to the Directorate, working with the Laboratory/Operational Managers to ensure effective budget management and monitoring at discipline level, workforce management and planning and ensuring effective use of resources and equipment. The Directorate General Manager plays a lead role in modernisation of the service in line with local and National strategies.

The Directorate General Manager has overall responsibility for ensuring that the Laboratory/Operational Managers manage CPA [UK] Ltd Accreditation compliance to ensure full accreditation is retained.

The Quality Coordinator [A7]
The Quality Manager ensures, on behalf of the Laboratory Management, that the Directorate's Quality Management System functions correctly.

The Quality Coordinator has a defined role for:

- Ensuring that a Quality Management System is implemented and maintained.
- Overall control of quality and advising and monitoring all aspects of quality within the Directorate.
- Arranging document control and maintenance.
- Planning and organising audits schedules.
- Ensuring that details of reviews are recorded.
- Ensuring the completion and discharge in the appropriate timescale of corrective actions resulting from audits.
- Reporting to Laboratory Management on the functioning and effectiveness of the Quality Management System.
- Co-coordinating the awareness of the needs and requirements of the users.

Laboratory/Operational Managers
There is a Laboratory Manager Operational Manager for each Pathology discipline having responsibility for operational, technical, quality and budgetary issues. They provide strategic leadership and day to day operational management of the non-clinical workforce within their

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discipline. The position has a lead role in managerial, educational, professional and technical issues within the department/discipline; in liaison with the Clinical lead Consultant of the department for clinical issues. This includes:

- Responsibility for the Technical development of the service in close collaboration with the lead Consultant of the Department.
- Development and promotion of Directorate wide working and standardization of operational policies, procedures and practices within the discipline and within the appropriate Pathology Directorate Management team.
- Contributing to the Pathology Directorate Management team to develop and implement the planning and performance management agenda for Pathology.
- Taking a lead role in the implementation of new techniques and facilitate research and development in collaboration with the lead Consultant of the Department.
- Overall responsibility for ensuring that CPA (UK) Ltd Accreditation compliance is maintained in their department.

Information and I.T. Systems Manager

- To act as Directorate Lead for Trust wide Information Technology.
- To be responsible for the IT development of the service and direct assessment of new software and hardware for the provision of effective IT solutions for the Trust wide Pathology service.
- To provide timely and accurate management and performance information as required by the Clinical Director, General Manager, members of the Pathology Management Team and users of the service.
- To develop systems to enhance the financial management of the Directorate.
- To collaborate with Trust IT services with regard to Trust wide and GP electronic reporting system.

Training Lead [B2.3b]

The remit of the Training Lead shall include the following items:

- To acquire and maintain suitable training for the requirements of the role including suitable knowledge of Trust policies on education and Training
- To be responsible for the monitoring of Pathology training activities
- To provide an annual update on educational, training and CPD activities to the Pathology Annual Management Review
- To foster an environment of continuing professional development by publicising CPD events and ensuring staff are aware of the IBMS CPD scheme and portfolio
- To ensure records of Pathology staff qualifications, competencies and CPD activities linked to personal development plans are maintained according to CPA Standard B6
- To liaise regularly with Departmental Training and Education Representatives on all aspects of training and education
- To liaise with the relevant external education provider

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- Liaison with IBMS for accreditation of in house CPD events
- Arranging speakers and providing their brief
- Providing the DVH Pathology in house CPD portfolio to staff where required
- Supporting Journal Based Learning
- To ensure that trainees are trained according to current HPC, IBMS, BSQR, HTA, ACB protocols and CPA Standard B9 and in a timely manner
- To monitor that new staff are inducted according to Pathology and Trust protocols Health and Safety Lead

Health and Safety Lead [B2.3c]

The remit of the Health and Safety Lead shall include the following items:

- To acquire and maintain suitable training for the requirements of the role
- To chair the Pathology Health and Safety Committee and lead on health and safety issues.
- To monitor the maintenance of health and safety standards
- To acquire and maintain suitable knowledge of Trust policies and procedures relating to health and safety, risk management and incident reporting
- To attend the Trust Health and Safety and Committee on behalf of Pathology
- To promote the education and training of staff in health and safety issues
- To maintain an up to date knowledge of health and safety legislation and publications
- To liaise with the Trust Health and Safety advisor, Risk Management team and Fire Officer
- To support audits relating to laboratory health and safety
- To ensure that Pathology is compliant with CPA standard C5, health and safety
- To provide an annual update on Health and Safety issues to the Pathology Annual Management Review

Transfusion Practitioner

The remit of the Transfusion Practitioner shall include the key aspects:

- To be the named key contact in Pathology with reference to use of blood and blood products in the Trust
- To monitor surgical activity with reference to provision of the transfusion service and prepare reports on trends as necessary
- To design and initiate audits concerning surgical issues
- To monitor and regularly audit the Integrated Care Pathway documentation for blood tracking as required by the BSQR.
- To devise and deliver training sessions as required by the BSQR to educate and encourage best practice in handling of blood components
- To monitor blood fating by regular audit
- To attend and report to the Hospital Transfusion Committee
- To be member of the Hospital Transfusion Team
- To report appropriately to SHoT and SABRE as required by BSQR

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Pathology Directorate [A1.5]

Pathology Directorate Meetings are scheduled to be held monthly

Function:

The Pathology Directorate meeting is the focus of management and service delivery and improvement within the Directorate. It oversees the governance of the Directorate and receives reports on Quality, IT, departmental, Health and Safety, and training.

Membership:

- General Manager .~ Chairperson
- Clinical Director
- DVH Clinical Lead for Pathology.
- Quality Coordinator.
- Information and IT Systems Manager.
- Departmental Lead Consultants
- Departmental Laboratory and Operational Managers. .
- Directorate Clinicians.

Pathology IT Steering Group. This group is scheduled to meet before and during IT projects.

Function:

- To co-ordinate and quality assure the design, configuration and standardisation of work that will be required to support the development of the core Pathology system for the Dartford and Gravesham NHS Trust.
- To produce policies and procedures for the management of the system and ensure that these have been fully ratified by the Trust.
- Ensure a consistent approach to all IT related matters.
- Ensure and integrate standardisation across all disciplines including:
  - Test requesting.
  - Report formats.
- To ensure that all relevant personnel are kept informed of any relevant changes.
- To monitor access levels assigned to IT systems.
- Ensure that changes made to IT systems that affect other systems are coordinated and controlled.

Membership:

- Information and Systems Manager ~ Chairperson
- Pathology General Manager.
- Chair of the OMG
- Training Lead for Pathology
- Ad hoc staff with existing system expertise
- Clinical Director – Pathology
- Clinical Representation - Acute Trust

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- Other Pathology Consultants as appropriate.
- Trust IMT Strategy Program Manager.

Pathology Operational Management Group [A1.5]

This group is scheduled to meet monthly with provision for ad hoc interim meetings as required.

Function:

- To review and monitor service delivery and operational strategy.
- Development of working relationships within and outside the Trust ~ including:
  - The Kent and Medway Pathology Network.
  - Liaison with service users.

- Performance ~ including:
  - Finance including budgets and savings.
  - Service delivery including turnaround times
- Human Resources including ~
  - Workforce issues – departmental and Directorate wide.
  - Workforce target performance including appraisals, training, sickness management.

Membership:

- General Manager.~ Chairperson
- Departmental Managers.
- Quality Coordinator
- Information and IT Systems Manager.
- Business Support Manager
- H.R. Business Partner.

Directorate Quality Management Group.

[Pathology Document 3923 ~ Pathology Quality Group Terms of Reference]

This group is scheduled to bimonthly

Function:

- Review of Quality Standards.
- Instigates Quality Improvement.
- Receives reports on levels of compliance to CPA (UK) Ltd and other Quality Standards.
- Identifies audit requirements and takes reports from audit activity.
- Reports to Directorate Management with high level quality/governance issues.
- Monitors Quality Assurance performance.
- Monitors departmental error logging.
- Monitors and leads Directorate and Discipline Quality Improvement Plans.

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Membership:

- Quality Coordinator ~ Chairperson
- Transfusion Practitioner.
- Directorate Clinical Audit Lead.
- Departmental Quality Representatives.

Directorate Governance Committee [formerly Directorate Risk Management Committee]

Function:

- Governance.
- Monitor, manage and review risk by discipline and Directorate.
- To discuss monitor and resolve incidents, complaints, Patient Advocacy Liaison service queries [PALS], quality alerts and Serious Incidents Requiring Investigation [SIRIs].

Membership:

- Transfusion Practitioner. ~ Chairperson
- Quality Coordinator
- Departmental Governance Representatives
- Trust Risk Representative.

Directorate Health and Safety Group

[Pathology Document 3911 ~ Terms of Reference ~ Pathology Health and Safety Group]

This group is scheduled to meet monthly.

Function:

- Receive Health and Safety reports from Departmental Staff Meetings with a view to planning and coordinating the provision of a safe environment in the laboratory for staff, patients and visitors.
- Communicate Health and Safety issues to the Pathology Directorate.
- Refer Health and Safety actions to Discipline Management Teams.

Membership:

- General Manager ~ Chairperson.
- Quality Coordinator
- Discipline Health and Safety Representatives.

Departmental Staff Meetings

Departmental Staff Meetings are scheduled to take place monthly and are open to all staff within the relevant department.

Function:

- To discuss service delivery
- To discuss IQA and EQA performance.
- To discuss departmental procedural/developmental issues.
- To discuss departmental Health and Safety issues.

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- To discuss departmental equipment issues.
- To discuss departmental staffing issues.
- To discuss Quality issues.

Directorate Training and Education Committee [TEC] [B9]
[Pathology Document 342 ~ Terms of Reference ~ Pathology Training and Education Committee]
This group is scheduled to meet monthly.
Function:

- Ensure that appropriate National education, training legislation and regulations and mandatory Trust requirements are maintained [B9.1a]
- Discuss the needs and provide direction to the process of staff education and training so that the demands of the service can be met [B9 1b, B9.2, B9.3, B9.4, B9.5]
- Monitor each discipline's training and education activity including CPD activity.
- Enable staff to meet their Knowledge and Skills Framework [KSF] responsibilities.
- Ensure that appropriate resources for staff training and education are available[B9.3]
- Monitor and advise on equitable opportunities for training and development.

Membership:

- Chairperson Rotational
- Departmental specific Training and Development Representatives.
- Quality Coordinator

If any of the above Leads is unable to attend any of the Trust meetings listed a designated deputy from within the Pathology Training and Education group or Pathology Health and Safety group will attend

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7. SECTION A

Organisation and Quality Management System

Organisation and Management [A1]

The Organisation and Management of the Pathology Directorate is detailed on Page 10 of this Quality Manual.

Needs and Requirements of Users [A2]

The needs of Users are under constant review. This is achieved by:

- Providing statistical information to the Trust, Commissioners, Strategic Health Authority (SHA) and other external agencies.
- Collaboration on Clinical Governance issues with Users.
- Regular User Questionnaires and Satisfaction Surveys. [A2.1]
    - Trust Users.
    - PCT Users.
    - Phlebotomy Users.
    - Mortuary Users.
    - Staff.
- User Newsletters.
- Analysis of complaints/suggestion logs leading to change/improvements in the Quality of the service delivered where necessary.

The needs of the Users are translated into requirements, which form the focus of Objective setting and planning [A5] within the Quality Management System. Assessment of User Satisfaction and Complaints [H1] is conducted regularly and consideration of the findings forms part of a dedicated Directorate Annual Management Review [A11] when Business Plans and Objectives are set as part of Service Redesign.

Quality Policy [A3]

The Quality Policy Statement is detailed on Page 7 of this Quality Manual.

The Quality Management System [A4]

The components and relationships within the Quality Management System are described throughout this Quality Manual and under LTD Standards v 2.01. A5 ~ A11

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Quality Objectives and Plans [A5]
The Quality Objectives for the Directorate are discussed, agreed and documented at the annual service review between the Trust Lead for Pathology and Senior Management Team for the Pathology Directorate.

The Laboratory Management Team defines the Quality Objectives [A5.1] of the laboratory in consultation with the individual disciplines and is responsible for ensuring that plans are made to meet these objectives. Discipline Management Reviews [see A11], that are undertaken annually, determine whether the objectives have been successfully completed and provides an opportunity for revision of such objectives and plans and the functioning of the Quality Management System. The Quality Objectives are integral to the Quality Policy of the Directorate and the plans designed to implement those objectives are fulfilled by the pre-examination, examination and post-examination processes [E, F, and G]

The Quality Objectives of each discipline are documented in their Quality Improvement Plan in accordance with the Directorates Continual Quality Improvement Policy.

Quality Manual [A6]
This Standard is fulfilled by the production of this Quality Manual. Personnel are familiar with and work to current versions of the quality manual and all referenced documentation and are required to record this as evidence of system knowledge. The Quality Manual is reviewed regularly, updated as required and any changes communicated to all personnel concerned.

Quality Manager [A7]
There is a full time dedicated Quality Coordinator for the Pathology Directorate who works with the Laboratory Management Team to ensure correct functioning of the Quality Management System [A7.2, A7.3] The Quality Coordinator is accountable to the Pathology General Manager.

Document Control [A8]
The Pathology Directorate uses Quality Management [QMS] iPassport software for Document Control. [Pathology Policy 747~ Control of Quality and Process Records]. [A8.1]. The procedures for Document Control include both internally generated and documents from external sources required for the Quality Management System [QMS] and are embedded in the QMS software that is used for all Directorate and Departmental documentation.

This ensures that:

- Documents are approved for use by authorised personnel prior to use. [A81.a]
- Documents contain a unique identifier, review date, date of issue, revision version, page x of y and the name of the author and authoriser. [A81b]

- There are readily accessible master lists that identify current revision status and distribution of documents in order to prevent the use of invalid and/or obsolete documents. [A81.c]
- Documents are legible, readily identifiable and retrievable. [A8.1d]
- Documents will be regularly reviewed and updated as appropriate.[A8.1e]

An outline of the structure of the documentation used in the Quality Management System is as follows:

o Audit	~ By Discipline.
o Forms	~ By Directorate and Discipline.
o Management Procedures	~ By Directorate and Discipline.
o Meeting Minutes	~ By Directorate and Discipline.
o Standard Operating Procedures	~ By Directorate and Discipline.
o Quality Documents	~ Quality Manual. ~ Quality Policy. ~ Quality Procedures.

Control of Process and Quality Records [A9]
Each discipline has established procedures for controlling process and quality records [A9.1] in accordance with the Royal College of Pathologists [RCPath] "Guidelines for Retention and Storage of Pathological Samples and Archives in Pathology Laboratories." and the

[Pathology Policy 2880 ~ Retention, Storage and Disposal of Quality and Process Records]. These procedures include;

- Identification and indexing. [A9.1.a]
- Security. [A9.1.b]
- Retention. [A9.1c]
- Storage and retrieval. [A9.1d]
- Disposal. [A1.9e]
- Compliance with WHC (2005) 066 Blood Safety and Quality Regulations. [A9.2]
- Compliance with Human Tissue Authority [HTA] Conditions of License. [A9.2]

Control of Clinical Material [A10]
Each discipline has established procedures for controlling clinical material [A10.1] in accordance with the Royal College of Pathologists [RCPath] "Retention and Storage of Pathological Samples and Archives in Pathology Laboratories." and the [Pathology Policy 2881 ~ Retention, Storage and Disposal of Clinical Material]. These procedures include;

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The procedures for the control of clinical material are contained in appropriate documents held on the QMS software and relate to:

- Identification and indexing. [A10.1a]
- Security. [A10.1b]
- Retention. [A10.1c]
- Storage and retrieval. [10.1d]
- Disposal. [A10.1e]

Management Review [A11]

[Pathology Policy 2912 ~ Policy and Procedure for Conducting Annual Management Review [AMR]

The management team within each discipline conducts an annual review, the content of which is detailed in the Directorate Annual Review Policy. Records are kept and key objectives for subsequent years are defined and plans formulated for their implementation.

- Reports from managerial and supervisory personnel.
- User satisfaction surveys and complaints.[H2]
- Clinical incidents and near misses.
- Internal audit of the QMS. [H3]
- Internal audit of examination processes. [H4]
- Clinical Audit. [H3, H4]
- Reports of assessment by external bodies.
- Status of preventative, corrective and improvement actions. [H6]
- Major changes in organisation and management resource [including staffing] or process.
- National benchmarking data. [A11.1f]
- Internal and External Quality Assurance. [H5]
- Follow up from previous management reviews.

The Laboratory Management participates in an annual service review with the Trust Lead Executive that provides a mechanism to review the following;

- Reports from managerial and supervisory personnel.
- Assessment of User satisfaction and complaints.[H2]
- Internal audit of the QMS.[H3]
- Internal audit of examination processes. [H4]
- External Quality Assessment reports. [H5]
- Reports of assessments by external bodies.
- Status of preventative, corrective and improvement actions. [H6]
- Major changes in organisation and management resources [including staffing] or process.

Records are kept and key objectives for subsequent years and plans formulated for their implementation.

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8. SECTION B

Personnel

Professional direction [B1]
The Clinical Director professionally leads the Directorate.

A consultant professionally leads each discipline:

Staffing [B2]
Staff records and evidence of appropriate professional qualifications are held securely by the appropriate Laboratory Manager within each discipline. These records are also held by the Trust Human Resources [HR] department.

The Pathology Management Team ensure that there are appropriate numbers of staff, with the required education and training to meet the demands of the service and the appropriate National legislation/requirements [B2.1].Registration of staff is in accordance with current National legislation and regulations [B2.2]

Staffing includes individuals with the following roles:

- Directorate Quality Coordinator ~. [A.7]
- Discipline specific Quality Representatives:
- Directorate Training Officer ~ Laboratory Manager [Rotational] [B9]
- Discipline specific Training Representatives:
- Directorate Health and Safety Officer ~ Laboratory Manager [Rotational] [C5]
- Discipline specific Health and Safety Representatives:

Personnel Management [B3]

The Directorate has a Human Resources Business Partner, assigned by the Trust, to assist with Personnel issues. The Directorate complies with all Human Resources Policies provided by the Trust. [Pathology Policy 2898 ~ Policy for Personnel Management]

The Pathology Directorate Management Team, through the Trust's Personnel Department has procedures for;

- Recruitment and Selection. [B3.1a] [Pathology Policy 2907 ~ Policy and Procedure for the Recruitment Process]
- Staff Training and Education [B3.1g] [B9] [Pathology Policy 2902 ~ Pathology Training Policy]

Grievance Procedures and Staff Disciplinary Action [B3.1h]
The Pathology Directorate follows the processes described in Trust Policies.

Staff Orientation and Induction [B4] [Pathology Policy 2890 ~ Staff Induction Policy]

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The Trust Staff Induction Policy is accessed via the Trust intranet site ~ Adagio. Pathology Directorate Induction manuals can be found in individual departments. New staff are invited to attend a two day Trust Induction course which is additional to local induction within the Pathology Directorate. Copies of Induction records are held by individual staff members and in departmental staff records held by the appropriate Line Managers.

Job Descriptions and Contracts [B5]
All staff job descriptions are produced using the Agenda for Change format and linked to staff members on the QMS software.

Job descriptions are discussed annually at Personal Development Reviews and are kept in individual personal records. All staff are issued with a contract of employment on entering service. Copies are held centrally by the Trust Personnel Department as well each individual member of staff.

Medical contracts are held by the Human Resources Department.

Personnel files and staff records [B6].
Each member of staff has a local personal file and staff records are maintained in accordance with Trust and Pathology Directorate Policy.

Staff records are kept for each member of staff and held securely, to maintain confidentiality, by each Line Manager and are continuously maintained and updated to include:

- Personal details.[B6.2a]
- Employment details. [B6.2b]
- Contact details.
- Job description.[B6.2c]
- Employment details.[B6.2d]
- Terms and conditions of employment. [B6.2d]
- Induction and Orientation record. [B6.2e]
- Absence record. [B6.2k]
- Sickness record.
- Accident record. [B6.2l]

Other appropriate records are kept as follows:

- Fire lecture attendance ~ recorded by Trust Education Department. [B6.2f]
- Education and Training, including Continuous Professional Development (CPD) recorded in Personal Portfolios and by the Directorate Education and Training Group. [B6.2g]
- Competency records ~ recorded in Personal Portfolios and/or individual Training Manuals [B6.2h]

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- Relevant educational and professional qualifications ~ records held by the Trust Personnel department. [B6.2i]
- Certification of Registration ~ Copy held by Trust Personnel department. [B6.2j]
- Annual joint Review record ~ held by General Manager and a copy in Personal Development Portfolio [B6.2m]
- Occupational Health record ~ held by Occupational Health department. [B6.2n]
- Disciplinary action records ~ held by Trust Personnel department for the appropriate time period. [B6.2o]

Individual Performance Review and Personal Development Plan [B7]
There is a Trust Policy for annual appraisal and development plans for staff that can be accessed via the Trust intranet site ~ Adagio.

All staff members have an annual appraisal and a joint review that includes;

- Stated objectives and plans of the Trust

- Stated objectives and plans of the relevant discipline.[B7.1a]
- Job description of the staff member. [B7.1b]
- Personal objectives of the staff member. [B7.c]
- Training and development needs of the staff member. [B7.1d]
- KSF Outline.

The Pathology Directorate operates a cascade system of appraisal, individuals being appraised by the next manager above the appraisee.

Only those staff who have attended a Trust training programme may perform an Annual Joint Review and the process is explained to all participating staff. [B7.2]

Records of Annual Joint Review are maintained by Department Managers in individual staff records. Copies are retained in individual staff portfolios. [B7.3]

The standard Trust documentation is used for documentation.

Staff Meetings and Communication [B8]
[Pathology Policy 2899 ~ Policy for Meetings and Staff Communication]
Communications between the Trust and the Directorate are maintained as follows;

- Trust Newsletter ~ Inside Issues.
- Staff Meetings.
- Chief Executives report.
- E-mail.
- Trust Risk Management Committee.
- Trust Health and Safety Committee.

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- Trust Financial Management Group.

Local communications between the Pathology Directorate and all departments are by regular Directorate and staff meetings. [B8.1]

Trust information, meeting minutes, items of interest, and news letters are displayed on Departmental and Staff Room notice boards throughout the Directorate. [B8.2]

Staff Training and Education [B9] [Pathology Policy 2902 ~ Pathology Training Policy]
The Biochemistry, Microbiology and Haematology and Blood Transfusion Laboratories are registered as Training Laboratories with the Health Professions Council (HPC) and have training and education programs in accordance with guidelines from the relevant professional and registration bodies. [B9.1a]

Training covers all aspects of work in the laboratories that each member of staff is required to carry out or participate in including the Quality Management System, the LIM system Health and Safety and Data Protection issues. [B9.2]

Staff have access to education and training commensurate with their needs and position within the organisation. Training plans are identified at annual review and as part of the Personal Development Plan. All Biomedical Scientist training staff are supported by a designated mentor within the department and follow the guidelines described in the Institute of Biomedical Science Training Portfolio. [B9.1b]

The Pathology Directorate has no dedicated financial resources to provide education and Continual Professional Development for training and trained staff. All requests are made through the Pathology Training and Education Group.

There are comprehensive library facilities within the Trust and staff has access to the Internet for scientific information. [B9.4]

Training records are held by each individual member of staff in their Personal Portfolio and by the Pathology Training and Education Group. Continual Personal Development records are held by each individual member of staff. [B9.5]

The Pathology Directorate has a designated Training Officer [B9.6] supported by departmental Education and Training Representatives [B9.6]

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9. SECTION C

Premises and Environment [C1]
The Laboratory provides accommodation and conditions for staff conducive to the proper performance of their respective duties in accordance with Statuary Regulations and Guidelines.

To ensure the quality of results of examinations laboratory areas containing equipment and reagents that may be affected by environmental factors such as temperature, dust, humidity etc. are continually monitored.

Facilities for Staff [C2]
There are adequate staff facilities within the Pathology Directorate. These include:

- Toilet and shower facilities.[C2.1a]
- Rest area with catering facilities and drinking water.[C2.1c]
- Changing rooms. [C2.1Ee]
- Secure storage for personal effects. [C2.e]
- Storage of personal protective clothing. [C2.1f]

Secure overnight accommodation is available for staff providing an Out of Hours service. [C2.2]

Trust staff facilities:

- Staff Dining Room
- Variety of shops.
- ATM facility.
- Gymnasium.
- Complementary Therapies.
- Health checks.

Facilities for Patients [C3]
There are patient facilities for general use within the Directorate as well as for the significant numbers of patients that attend the Phlebotomy area. These facilities are consistent with their intended use.

Facilities for Storage [C4]

There are areas of storage located throughout the Directorate. Separate, external storage containers are provided for the storage of flammables, in accordance with Health and Safety Executive [HSE] recommendations and fire regulations. There is controlled refrigerated storage space for reagents, samples and other material as required. Storage facilities for Blood and Blood Products meet the requirements as described by MHRA ad BSQR.

Health and Safety [C5]

It is the Pathology Directorates policy to provide and maintain a safe and healthy working environment for all its employees and visitors. The term 'visitors' includes Trust staff undertaking their normal duties, those delivering goods, contractors, company representatives, other visiting professional groups, patients delivering samples, having samples taken or visiting Consultants. The Pathology Directorate complies with the Trust Health and Safety Policy and each discipline has its own Health and Safety Policy that is held on the QMS software. Each Health and Safety Policy details procedures [C5.3] for:

- Action to be taken in the event of fire.[C5.3a] [Pathology Policy 647 ~ Fire and Evacuation Policy]
- Action to be taken in the event of a major spillage of dangerous chemicals or clinical material. [C5.3b]
- Action to be taken in the event of an inoculation accident. [C5.3c]
- Reporting and monitoring of accidents and incidents. [C5.3d] [Pathology 7188 ~ Incident Reporting SOP]
- COSHH and Risk Assessments. [C5.3e]
- Disinfection processes. [C5.3f]
- Decontamination of equipment. [C5.3g]
- Chemical handling. [C5.3h]
- Storage and disposal of waste.[C5.3i]
- Specimen collection and handling, transportation, reception and referral to other laboratories. [C5.3j] [Pathology Policy 2888 ~ Transport of Pathological Samples] [Pathology Policy ~ 2894 ~ Sample Referral]

Laboratory containment facilities conform to the Advisory Committee for Dangerous Pathogens [ACDP] [C5.4]

Guidelines and safety notices are posted throughout the Directorate to advise staff of relevant risks and safe practices required. [C5.5]

Annual Safety Audits are undertaken in all departments in Pathology and the results discussed formally at Pathology Directorate Health and Safety Committee meetings.

Risk assessments and CoSHH data is cross referenced to procedures on the QMS software and is available to all staff.

Staff are made aware of their responsibilities for Health and Safety [C5.2] in:

- Contract of employment.
- Induction training.
- Job descriptions.

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- Departmental Health and Safety Manuals [Pathology Document 278 ~ Blood Sciences ~ Health and Safety Manual] [Microbiology 280 ~ Health and Safety Manual]

All staff are required to attend regular Health and Safety Update programs provided by the Trust. Records of attendance are kept by the Trust Education and Training department and by the Directorate Education and Training Group.

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10. SECTION D

Equipment, Information Systems and Reagents

Management of Equipment [D1]

The Directorate has an annual plan that identifies new and equipment replacements ensuring that quality and capacity is addressed and meets the needs of its users. [D1.2]

The Directorate complies with National guidelines and the Trust policy for purchase, installation, training and safe disposal of all equipment. It also complies with Trust National and EU policies for standing orders, tendering and contract procedures and standing financial instructions that includes compliance with legislation for:

- Fair competitive tendering.
- Value for money.
- Suitability and ease of use.

The process for the validation of new equipment is described in the Pathology Policy 847 Policy and Procedure for the Procurement and Disposal of New Equipment and is in accordance with the Trust Policy.

The Procedure for procurement and management of equipment is held on the QMS software and includes:

- Assessment of justification of need.[D1.2a]
- Selection. [D1.2b]
- Acceptance. [D1.2c]
- Training. [D1.2d]
- Preventive maintenance, service and repair. [D1.2e]
- Calibration and monitoring of instruments, reagents and analytical systems. [D1.2f]
- Decontamination. [D1.2g]
- Recording of instrument failure and subsequent corrective actions. [D2.1h]
- Planned replacement taking into consideration of energy use and care of the environment. [D2.1i]
- Disposal of equipment ensuring that Trust Policies are followed.
- Adverse incident and vigilance reporting. [D1.2j]

There is an inventory of equipment [D1.3] held on the QMS software that includes:

- Name of manufacturer. [D1.3a]
- Model name and/or number.
- Serial number. [D1.3b]
- Date of purchase or acquisition. [D1.3c]
- Record of contract maintenance. [D1.3e]

- Record of equipment downtime. [D1.3f]

Laboratory staff will only be permitted to use equipment unsupervised when the appropriate senior member of staff has established that they are competent and confident to do so. This will be documented accordingly in the individual's training record.

Electrical safety checks are carried out regularly and all equipment is marked, identifying the last inspection date and when the next inspection is due. Where appropriate, equipment will be regularly maintained by hospital engineers or through a maintenance contract with external engineers. When it is necessary for equipment to be commissioned and/or calibrated prior to use, this will be carried out either in-house or by a relevant body as appropriate. Manufacturer's operating manuals and maintenance manuals are held in the relevant section of the laboratory.

Management of Data and Information [D2]
The Pathology Directorate Information and Systems Manager is responsible for the management of such data. The Directorate utilises a Laboratory Information System [LIMS] to record and store patient information. Access to electronic data is controlled and restricted by individual password security and assigned privilege rights, thus maintaining confidentiality and data protection. [Pathology Policy 2887 Management of Data and Information] [Pathology Pathology 2908 ~ Policy and Procedure for the Management of Miscellaneous Information and Records]The system is backed up daily and the backup tapes are safely and securely stored by the Trust Information Technology department. Procedures detailing the use of the LIMS are held on the QMS software.

The Directorate complies with:
- The Data Protection Act.
- The Caldicott Principles.
- Freedom of Information Act.

Management of reagents, calibration and control materials [D3]

The Directorate ensures the funding and availability of adequate and suitable materials required to provide a quality service for users [D3.1, D3.2, and D3.3]. Procedures for the management of reagents, calibration and quality control material are held on the QMS software [Pathology Policy 2891 Management of Reagents, Calibration and Controls] and include:

- Selection, purchasing and ordering.[D3.2a]
- Assessment of suppliers. [D3.2b]
- Receipt and verification of identity and condition. [D3.2c]
- Issue and inventory management. [D3.2d]
- Risk assessment through classification of hazard and exposure potential and assignment of handling precautions if appropriate. [D3.2e]
- Safe disposal. [D3.2f]

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Reagents and materials are labeled, when appropriate, with date of receipt, lot number, first use and expiry date. Records of the management of reagents, calibration and quality material are kept with individual analysers, either as a manual record or one embedded within the analyser information system. [D3.3]

Risk and COSHH assessment records are held on the QMS software with the appropriate procedures.

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11. SECTION E

PRE-EXAMINATION PROCESS

Information for users and patients [E1]
Information for the users of the service is found in discipline specific Laboratory Users Handbooks located on the Trust internet site and the Trust intranet site ~ Adagio. These Handbooks provide information on the location and opening times of the department, instructions for completing request forms, submitting samples and the repertoire of each discipline in listed in each Handbook. Contact information of key members of staff and the availability of clinical advice and interpretation is also included. Each Handbook is under constant review and updated regularly [E1.1]

The Request Form [E2]
The request forms are designed to provide all relevant information required to provide a safe and meaningful report including clinical advice and to satisfy minimum internal audit requirements.

Haematology and Biochemistry have a combined Blood Science request form. Microbiology and Blood Transfusion have separate dedicated request forms. Separate dedicated forms are available for Histopathology/Non-Gynaecological Cytology referred samples. A National request form is used for the Cervical Screening Program samples.

The request forms provide space for:

- Sufficient information to allow unequivocal identification of the patient [E2.1a].
- Identification of the location and of the requesting individual.[E2.1b]
- Date and time of specimen collection.[E2.1c]
- Type of specimen and anatomical site of origin if relevant. [E2.1d]
- Investigation required. [E2.1e]
- Priority status. [E2.1h]
- Date and time of receipt of sample by the laboratory. [E2.1f]
- Relevant clinical information. [E2.1g]
- Location for dispatch of results. [E2.1j]
- Laboratory accession number. [E2.1j]

Samples that do not meet the minimum requirements described in the Directorate Policy for the Acceptance and Rejection of Pathological Samples [Pathology Policy 2882] are dealt with in the manner described in this Policy. This policy is held on the QMS software and is supported by departmental SOPs.

Users are invited to comment on the ease of requesting via the annual User Satisfaction Survey carried out by the Quality Manager.

Specimen Collection and Handling [E3]
The procedures for the collection and handling of pathological samples are held on the QMS software. [Phlebotomy SOP 7428. The Phlebotomy Procedure]

The procedures for collection and handling of pathological procedures are available to the users on request and copies are held by the Phlebotomy and Phlebotomy support staff. [E3.2]

Sample volumes are reviewed regularly by the Management Teams in each department to ensure that either insufficient or excessive amounts of samples are collected. [E3.3]

Specimen Transportation [E4]
Information and advice is available, for all users of the service, in the Departmental Handbooks on the Trust Intranet site ~ Adagio and the Trust Internet Site. This information includes how samples should be transported to the laboratory, including labeling and packaging and also gives time frames to ensure that samples arrive in optimum condition for analysis. [E4.1] [Pathology Policy 2888 Transport of Pathological Samples]

Transport of Hospital Samples
The Pathology Directorate uses an Air Tube system, with Pods, to receive samples from the following areas of the hospital: [Blood Science Central Reception Procedure 33963 Use of the Pneumatic Delivery Tube System]

- Accident and Emergency Department [AE]
- Urgent Care Centre. [UCC]
- Intensive Care Unit [ITU]
- Special Care Baby Unit [SCBU]
- Phlebotomy Department.
- Haematology Medical Ward including Chemotherapy Day Care Unit.
- Surgical Assessment Unit [DCU]

In addition, hospital porters collect samples from all wards and departments three times per day at pre-arranged times agreed by the Pathology Directorate and the Head Porter. [Pathology Document 145 ~ Model Rules for Porters] Urgent samples are also collected by porters from all areas, following a telephone request from the ward/department.

The following samples/items are not suitable to be transported by the Air Tube system;

- Blood Cultures.
- Blood Gases.
- Blood Units and/or Blood Products.
- Large volume samples [24 hour urine samples].
- Post.

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Histology:

For Health and Safety reasons specimens in formalin preservative MUST NOT be transported via the Air Tube system.

External Sample Transportation

Samples regarded as external come from GP surgeries and from the phlebotomy service provided at Gravesend and North Kent Hospital and other external Pathology Service Users. A dedicated transport service operated by Carillion [PFI] collects these samples daily.
[Pathology Document 144 ~ Model Rules for Drivers]
Samples referred to other laboratories are transported by a variety of means that conform to legislative regulations.

Specimen Reception [E5]
All samples are received into the Blood Science Central Sample Reception (CSR) area. Microbiology and Blood Transfusion samples are redirected to the relevant departments. Cytology and Histopathology samples are received and dispatched from CSR.

The [Pathology Policy 2882 ~ Sample Acceptance and Rejection] is supported by departmental procedures for specimen reception of all samples. Mastercopies are held on the QMS software with hardcopies available at the point of use and include:

- Linking the request form to the sample [including secondary samples] [E5.1a]
- Recording of the date and time of receipt into the laboratory [E5.1c]
- Handling urgent samples.[E5.1d]
- Bar code labeling of samples and request forms.
- Ensuring staff safety.[E5.1e]
- Data entry onto the LIMS.[E5.1b]
- Processing of unacceptable samples and/or request forms. [E5.2a]
- Criteria for returning and recording samples to requestor [“precious samples”] [E5.2c]

Requests are reviewed at Departmental Management Reviews to ensure the appropriateness and suitability of examinations and methods of analysis. [E5.3]

Referral of Samples to other Laboratories [E6] [Pathology Policy 2894 ~ Sample Referral]
Departmental procedures for sample referral by each laboratory are held on the QMS software and include:

- Evaluation and selection of referral laboratories [E6.1a]
- Maintaining a record of all referral laboratories and the relevant repertoire.[E6.1b]
- Maintaining a record of all samples referred. [E6.1c]
- Recording of dispatch dates. [E6.1d]

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- Monitoring the return of reports from the referral laboratories or referral consultant. [E6.1e]
- Regular reviewing referral laboratories CPA [UK] Ltd status, EQA performance and turn around times to ensure that requirements continue to be met. [E6.1g]

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12. SECTION F

EXAMINATION PROCEDURES

Selection and Validation of Examination Procedures [F1]
Examination procedures within the Pathology Directorate are selected to ensure that suitable investigations are available for clinicians to both diagnose and monitor patients and meet the Royal College of Pathologists minimum data set.

Blood Transfusion procedures are designed to be suitable for the safe selection of blood and blood products and meet the requirements of both CPA [UK] Ltd and BSQR.

Mortuary procedures are designed meet the requirements of both CPA [UK] Ltd and HTA Condition of Licence.

Examination procedures are validated prior to their introduction to routine use. Departmental validation procedures are held on the QMS software.

Copies of all procedures are held on the QMS software. Hard copies are available in the relevant areas of the Pathology Directorate.

Examination Procedures [F2]
[Pathology Document 3887 ~ Standard Operating Procedure [SOP] Template]
Procedures for all examinations carried out in the Pathology Directorate are held on the QMS software and include, when relevant;

- Clinical relevance/purpose of the procedure. [F2.1a]
- Principle of the examination. [F2.1b]
- Sample requirements and means of identification and transport requirements. [F2.1c]
- Equipment reagents and materials. [F2.1d] [F2.1e]
- Calibrants and Internal Quality Control materials. [F2.1f] [F2.1j]
- Instructions for performance of the examination. [F2.1g]
- Limitations and pitfalls of the examination. [F2.1h]
- Recording and calculation of results. [F2.1i]
- Reporting reference limits. [F2.1k]
- Alert/critical values when appropriate. [F2.1l]
- Responsibilities of personnel for authorizing, reporting and monitoring reports. [F2.1m]
- Health and Safety requirements. [F2.1n]
- Performance criteria. [F2.1o]

Assuring the Quality of Examinations [F3]

There are procedures in place in each department for Internal Quality Control [IQC] to ensure the quality of all laboratory examinations. Records are maintained of the date, source and storage requirements of IQC material. Instructions for validation of this material are included. Procedures for External Quality Assessment [EQA] are in place for as many assays as schemes available [F3.1g]. This provides a comparison of local results and methods with those from other laboratories.

Results of IQC and EQA are made available to all staff and are fixed agenda items at all departmental staff meetings. Discrepancies are recorded and investigated when results fall outside limits set by test algorithms. [F3.2e]

[Pathology Policy 2884 ~ Preventive and Corrective Action and Continual Quality Improvement]

Methods are assessed to identify areas that have the potential to introduce variation. Control measures are applied as appropriate to reduce any uncertainty with regard to consistency and accuracy of results. [F3.1d]. Refer to [Pathology Policy 2883 ~ Determination of Uncertainty] supported by departmental procedures.

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13. SECTION G

POST EXAMINATION PROCESS.

Reporting results [G1]
The Pathology Directorate has determined, in consultation with its users departmental procedures for reporting results. Mastercopies are held on the QMS software and include:

- The report. [G1.1a]
- The telephoned report. [G1.1b]
- The amended report. [G1.1c]
- Clinical advice and interpretation. [G1.1d]
- Mechanisms for informing the requestor if an examination that could compromise patient care is delayed [G1.1e]

The Pathology Directorate has determined, in consultation with its users, Turn Round Times for examinations that reflect clinical need. They are monitored for non-conformities, by Laboratory Managers and, if appropriate, remedial or corrective action put into place.
[Pathology Policy 2884 ~ Preventive and Corrective Action and Continual Quality Improvement]

The Report [G2]
Reports are issued for all samples received in the Pathology Directorate and are formulated so that they are clear, unambiguous and contain sufficient information for the user to interpret the results [G2.1]. The report contains the following information:

- The Laboratory name. [G2.1a]
- Unequivocal identification of the patient. [G2.1b]
- Requestor and/or address for delivery. [G2.1c]
- Type of sample and date and time of collection. [G2.1d]
- Date and time of report. [G2.1e]
- Results, including reasons if no examination has been performed. [G2.1f]
- Reference limits as appropriate. [G2.1g]
- Interpretative comments as appropriate. [G2.1h]
- Highlighting of abnormal results. [G2.1i]
- Status of report as appropriate e.g. copy, interim or supplementary. [G2.1j]
- When possible, the identity of the authoriser[s] of the report. [G2.1k]

Reports or letters issued following the receipt of a report from a referral laboratory [G.2.4] additionally include:

- Identification of the referral laboratory. [G2.4a]
- All results [G2.4b]
- Interpretive comments from the referral laboratory, if appropriate. [G2.4c]
- Verification of transcription of results from referral laboratories. [G2.4d]

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There are departmental procedures in place to ensure confidential handling and transmission of results. [G2.5]

The Telephoned Report [G3]
The procedure for telephoned and faxed reports is held on the QMS software [Pathology Policy 846] and includes the following:

- The circumstances in which reports may be given by telephone. [G3.1a]
- Nominated personnel authorised to give reports by telephone. [G3.1b]
- Individuals that may receive telephoned reports and means of their identification. [G3.1c]
- Method of identification of the patient between reporter and receiver. [G3.1d]
- Confirmation of correct transmission. [G3.1e]
- The method of recording the event. [G3.1f]
- Maintenance of confidentiality.[G3.1g]
- Mechanism of sending a hardcopy report if required. [G3.1h]

The Amended Report [G4]
The procedure for issuing an amended report (one that is changed in any way following the issue of the initial report) [Pathology Policy 846] is held on the QMS software and includes:

- The criteria for issuing an amended report. [G4.1a]
- Personnel authorised to issue an amended report. [G4.1b]
- Identification to the user of an amended report. [G4.1c]
- Process for recording the issue of an amended report. [G4.1d]
- The reason for the issue of an amended report. [G4.1e]
- The instigation of preventative action if required. [G4.1f]
- The process to archive amended reports. [G4.1g]

Clinical Advice and Interpretation [G5]
The Pathology Directorate ensures that advice on investigations and the interpretation of results meets the needs of its users and also ensures that users have access to laboratory advice at all times. [G5.1] Clinical advice and interpretative comments are provided by suitably qualified biomedical and medical staff as appropriate and are provided in a clear unambiguous manner. [G5.2] [G5.3]

The Pathology Directorate ensures that there is systematic communication between the laboratory and clinical staff to promote effective utilization of laboratory services and to consult on scientific and logistical matters. When appropriate, records are kept of such meetings.

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14. SECTION H

EVALUATION AND QUALITY ASSURANCE

Evaluation and Improvement Processes [H1]
Ongoing evaluation and improvement processes are essential to ensure that the service provided by the Directorate meets the needs and requirements of its users. Recording, analysis and interpretation of the evaluation data is an important element of the Directorate of the Directorate management process and as such forms part of discipline specific Management Reviews. [A11, H1.3]

Evaluation of the service is achieved through:

- Assessment of User satisfaction and complaints [H1.1a] [H2]
- Internal audit of examination procedures [H1.1c] [H4]
  [Pathology SOP 700 ~ Performing an Internal Audit]
- Internal audit of the Quality Management System [H1.1b] [H3]
  [Pathology SOP 700 ~ Performing an Internal Audit]
- External quality assessment [H5]
- Reports from external bodies.
- Quality improvement including corrective and preventive action including the monitoring of quality indicators. [H6].
  [Pathology Policy 2884 Preventative and Corrective Action and Continual Quality Improvement.]
- Identification and control of non-conformities
  [Pathology Policy 2879 Identification and Control of Non-Conformities]

Results of evaluation and improvement are made available to all staff through staff and other Pathology Group meetings. Users are informed by Pathology representation at various user meetings and forums and news letters. [H1.2]
The analysis and recording of evaluation and improvement processes form a standard agenda item at departmental Annual Management Reviews. [H1.3]

Assessment of User Satisfaction and Complaints [H2]
The Directorate is committed to assessing user satisfaction and monitoring of complaints to ensure that the service provided by the Directorate meets the needs and requirements of its users. This is achieved by listening to and seeking information from the service through:

- User Questionnaires.
- Meeting with users, both internal and external to the Trust.
- Periodic User Newsletters.

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The Directorate investigates all complaints, in line with the Trust Complaints Policy, received from users and other parties and any anomalies identified relating to the Directorates accredited activities [H2.1A]

Records are maintained by the General Manager of any such complaints and anomalies and of resulting actions taken by the Directorate and will be an agenda item at departmental Annual Management Reviews.

The Directorate endeavors to meet performance targets such as turn around times in all areas [H2.1b]

The Directorate assesses the clinical relevance of laboratory investigations performed and the reliability of interpretative reports in conjunction with its users [H2.1c]

The Directorate participates in the evaluation of clinical effectiveness, audit and risk management activities of the Trust and relevant external bodies [H2.1d]

Internal Audit of the Quality Management System [H3]
The Directorate uses internal audit to provide evidence that the Quality Management System is implemented, effective and maintained throughout the Directorate. [H3.1]

Audit of the Quality Management System in each discipline is carried out annually by the Quality Manager using a specifically designed proforma. [H3.2]

- Audit findings, non-conformities, recommendations and time scales for corrective and preventive actions are documented. [H3.3]
  [Pathology Policy 2884 Identification and control of non-conformities.]

The results are discussed and reviewed as part of a standard agenda item at the Directorate Quality Management Group and with other relevant groups. [H3.4]

Internal Audit of Examination Process [H4]
Each discipline within the Pathology Directorate maintains a program of audit [H4.1]

Audits are performed according to the Audit Programs produced by the Quality Team (Quality Coordinator and discipline representatives). They are carried out by appropriately trained and competent members of staff. Vertical, Horizontal and Examination (Witness) audit tools are used. [H4.2]

Audit findings, non-conformities, recommendations and time scales for corrective and preventive actions are documented. [H4.3]
[Pathology Policy 2884 Identification and control of non-conformities.]

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The results are discussed and reviewed as part of a standard agenda item at the Directorate Quality Management Group and with other relevant groups. [H4.4]

External Audit Assessment [H5]
Each discipline within the Pathology Directorate participate in approved External Quality Assessment Schemes appropriate to the examinations and interpretations provided [H5.1]. Records of performance in these schemes are maintained by the laboratory management teams, [H5.2], reviewed and communicated to staff as a regular agenda item at departmental staff meetings. When decisions are taken by disciplines in relation to their performance, these are recorded, acted on and monitored [H5.3]. In instances where an appropriate External Quality Assurance Scheme does not exist and no other formal inter- laboratory comparison program is available, disciplines develop a mechanism to establish the acceptability of those procedures that are not externally evaluated [H5.4]

External Quality Assurance reports are displayed on relevant departmental notice boards.

Additionally the Pathology Directorate receives reports and acts on information from a wide range of external quality assessments including:

- Clinical Pathology Accreditation [UK] Ltd.
- Human Tissue Authority.
- Medicines and Healthcare Products Regulatory Agency.
- National Institute of Clinical Excellence.
- National Health Service Frameworks.
- National Patient Safety Agency [NPSA]
- Health and Safety Executive.
- Institute of Biomedical Science.
- MDA reports.
- NHS Cervical Screening Program EQA Scheme.

Quality Improvement [H6]
The Pathology Directorate maintains a Quality Improvement Program that is formulated and documented by the Pathology Directorate Management Team. [H6.1]

The policy for Corrective and Preventative Action and Continual Quality Improvement [Pathology Policy 2884] is held on the QMS software and include: [H6.2] [H6.3]

- Investigation of Root Cause Analysis of non-conformities and recording of results. [H6.2a]
- Determination of and responsibilities for corrective action. [H6.2b]
- Implementation of corrective action within agreed timescales. [H6.2.c]
- Monitoring of corrective actions taken. [H6.2d]
- Investigation of the causes of potential non-conformities. [H6.3a]
- Determination of and responsibilities for corrective action. [H6.3b]

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- Implementation of preventive action within agreed timescales. [H6.3.c]
- Ensuring that preventive actions taken are effective recorded and submitted for Management Review. [H6.3d]

Appropriate Quality Indicators are identified and established by the Directorate Management Team to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post examination processes. [H6.4]

The results of the Quality Improvement Programs are included in staff meetings and form part of the development, training and education of staff. [H6.5]

Identification and Control of Non-Conformities [H.7]
Procedures to ensure that non-conformities in pre-examination, examination and post-examination processes are identified and effectively managed to minimise risks to users are held on the QMS software. [H.7]

These include:

- Means of identification of non-conformances. [H7.1]
- Designation of responsibilities for management of non-conformances. [H7.1a]
- Definitions of remedial actions to be taken. [H7.1b]
- Actions to be taken:
    - Halting of examination and with holding reports. [H7.1c]
    - Medical significance and notification of user if appropriate. [H7.1d]
    - Identification and recall of released reports if appropriate. [H7.1e]
- Definition of responsibility for authorisation of the resumption of examinations. [H7.1f]
- Documentation of non-conformities and review to identify trends and initiate corrective action. [H7.1g]

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Appendix

Links

Please note: links are only correct at time of printing

Linked to Controlled Document

- **Document**: **Pathology - 188: Pathology Directorate - Statement of Quality Policy.** *v1.3* (Authorised)
- **Document**: **Pathology - 3914: Delegation of Clinical Director Responsibilities** *v1.2* (Superseded)
- **Document**: **Pathology - 3886: Pathology Directorate Quality Manual.** *v1.7* (Superseded)
- **Document**: **Pathology - 3886: Pathology Directorate Quality Manual.** *v1.8* (Superseded)
- **Document**: **Haematology 1306: Haematology & Blood Transfusion (includes Mortuary) CPA Application 2013** *v1.0* (Authorised)
- **Document**: **Pathology - 3914: Delegation of Clinical Director Responsibilities** *v1.3* (Authorised)

Document Revision History

Superseded on 30-Apr-2013 17:03 by Emma Clenshaw

Version 1.8 superseded by version 1.9

Authorised on 30-Apr-2013 17:03 by Emma Clenshaw

Authorised version 1.9 - inlcuded updating manual as cell path have left the pathology directorate. The following users will be notified when a review is due for this document: Emma Clenshaw

Draft Created on 10-Apr-2013 16:42 by Emma Clenshaw

Reason: overdue review date, requires updating of staff structure

Superseded on 04-Dec-2012 09:09 by Tina Green (Inactive)

Version 1.7 superseded by version 1.8

Authorised on 04-Dec-2012 09:09 by Tina Green (Inactive)

Authorised version 1.8 - REMOVE HAEM/BT CPA ACCREDITATION STATUS PAGE 3

. The following users will be notified when a review is due for this document: Tina Green

Draft Created on 20-Sep-2012 09:56 by Tina Green (Inactive)

Reason: REMOVE HAEM/BT CPA ACCREDITATION STATUS PAGE 3

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Superseded on 07-Jun-2012 21:14 by Tina Green (Inactive)

Version 1.6 superseded by version 1.7

Authorised on 07-Jun-2012 21:14 by Tina Green (Inactive)

Authorised version 1.7 - MINOR CHANGES TO REFLECT RETIREMENT OF CLINICAL DIRECTOR. QUALITY GROUP FREQUENCY CHANGED TO BIMONTHLY. MINOR AMENDMENTS TO GRAMMAR. The following users will be notified when a review is due for this document: Sophie Glew, Tina Green

Draft Created on 05-Jun-2012 22:01 by Tina Green (Inactive)

Reason: Amendment to Organisational Chart to reflect current structure.

Minor grammatical amendments to text

Superseded on 31-Oct-2011 15:54 by Tina Green (Inactive)

Version 1.5 superseded by version 1.6

Authorised on 31-Oct-2011 15:54 by Tina Green (Inactive)

Authorised version 1.6 - DOCUMENT REFERENCES UPDATED ONLY. NO CHANGES TO TEXT. The following users will be notified when a review is due for this document: Tina Green

Draft Created on 24-Sep-2011 11:32 by Tina Green (Inactive)

Reason: Update with document references

Superseded on 13-Feb-2011 13:58 by Tina Green (Inactive)

Version 1.1 superseded by version 1.5

Superseded on 13-Feb-2011 13:58 by Tina Green (Inactive)

Version 1.2 superseded by version 1.5

Superseded on 13-Feb-2011 13:58 by Tina Green (Inactive)

Version 1.3 superseded by version 1.5

Superseded on 13-Feb-2011 13:58 by Tina Green (Inactive)

Version 1.4 superseded by version 1.5

Pathology Directorate Quality Manual. - Version: 1.9. Index: Pathology - 3886. Printed: 12-Jun-2013 10:04

Authorised on 13-Feb-2011 13:58 by Tina Green (Inactive)

Authorised version 1.5 - . The following users will be notified when a review is due for this document:

Tina Green

Superseded on 13-Feb-2011 13:58 by Tina Green (Inactive)

Version 1.0 superseded by version 1.5

Draft Created on 13-Feb-2011 12:08 by Tina Green (Inactive)

Reason: UPDATE OF ORGANISATIONAL CHART ˜ PAGE 11

Review Set on 20-Dec-2010 12:00 by Sophie Glew (Inactive)

Review date set to 20-Dec-2011 - Comments:

There are still two descriptives for Biochemistry, i.e. Biochemistry and Chemical Pathology. This compromises the quality of our information and documentation. We must agree which to use and update all documentation, including website, handbooks, etc. Need our Clinical Director to agree.

Otherwise read and understood. . The following users will be notified when a review is due for this document:

Sophie Glew, Tina Green.

This document was originally due for review on 20-Dec-2010.

Superseded on 20-Dec-2009 17:22 by Tina Green (Inactive)

Version 1.1 superseded by version 1.4

Superseded on 20-Dec-2009 17:22 by Tina Green (Inactive)

Version 1.2 superseded by version 1.4

Superseded on 20-Dec-2009 17:22 by Tina Green (Inactive)

Version 1.3 superseded by version 1.4

Authorised on 20-Dec-2009 17:22 by Tina Green (Inactive)

Authorised version 1.4 - . The following users will be notified when a review is due for this document:

Tina Green

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Superseded on 20-Dec-2009 17:22 by Tina Green (Inactive)

Version 1.0 superseded by version 1.4

Draft Created on 20-Dec-2009 17:05 by Tina Green (Inactive)

Reason: To amend as follows:

1. Page 3 Senior Team Leader to Laboratory Suport Services Manager
2. Page 3 Add Haematology and Blood Transfusion fully CPA[UK] Accredited
3. Page 5 Add Cellular Pathology fully CPA[UK] Accredited
4. Page 11 Amend Organisational Chart - Laboratory Suport Services Manager
5. Page 17 Amend - Chair of Health and Safety Group to Laboratory Manager [Rotational]
6. Page 18 Amend - Chair of Education and Training Group to Laboratory Manager [Rotational]
7. Page 23 Remove named individuals
8. Page 24 Add Stated objectives and plans of the Trust
9. Page 40 Add National Patient Safety Agency [NPSA]

Superseded on 28-May-2009 16:22 by Tina Green (Inactive)

Version 1.0 superseded by version 1.3

Superseded on 28-May-2009 16:22 by Tina Green (Inactive)

Version 1.1 superseded by version 1.3

Superseded on 28-May-2009 16:22 by Tina Green (Inactive)

Version 1.2 superseded by version 1.3

Authorised on 28-May-2009 16:22 by Tina Green (Inactive)

Authorised version 1.3 - . The following users will be notified when a review is due for this document:

Tina Green

Draft Created on 28-May-2009 16:01 by Tina Green (Inactive)

Reason: To amend Pathology Organisational Structure to reflect changes in Line Management

Superseded on 13-Oct-2008 09:46 by Tina Green (Inactive)

Version 1.0 superseded by version 1.2

Pathology Directorate Quality Manual. - Version: 1.9. Index: Pathology - 3886. Printed: 12-Jun-2013 10:04

Superseded on 13-Oct-2008 09:46 by Tina Green (Inactive)

Version 1.1 superseded by version 1.2

Authorised on 13-Oct-2008 09:46 by Tina Green (Inactive)

Authorised version 1.2 - . The following users will be notified when a review is due for this document:

Tina Green

Draft Created on 05-Sep-2008 08:53 by Tina Green (Inactive)

Reason: Amendments required following CPA visit - Darren Edwards

Superseded on 02-Sep-2008 09:45 by Tina Green (Inactive)

Version 1.0 superseded by version 1.1

Authorised on 02-Sep-2008 09:45 by Tina Green (Inactive)

Authorised version 1.1 - . The following users will be notified when a review is due for this document:

Colin Farquhar, Tina Green

Draft Created on 02-Sep-2008 09:37 by Tina Green (Inactive)

Reason: To amend ommissions on page 17

Authorised on 02-Sep-2008 09:23 by Tina Green (Inactive)

Authorised version 1.0 - . The following users will be notified when a review is due for this document:

Colin Farquhar, Tina Green

Creation on 02-Sep-2008 09:14 by Tina Green (Inactive)

New Document created

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