Department of Musculoskeletal Pathology

Quality Manual – ISO 15189

Document Code	Approved Controlled Copy
MP01	
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Reviewed by:	Satveer Kaur (Histology Laboratory Manager)
Update Responsibility:	Pathology / Laboratory Manager
Relevant Standard:	• ISO 15189:2012 Standards : **4.2.2.2**

Contents

1. General Information

The Royal Orthopaedic Hospital NHS Foundation Trust) is the sole legal entity for the Support Services Division in which sits the Department of Musculoskeletal Pathology and is held legally responsible for its activities **(4.1.1.2)**. The Royal Orthopaedic Hospital NHS Foundation Trust is one of the largest specialist orthopaedic units in Europe offering planned orthopaedic surgery to people locally, nationally and internationally.

Since 1877 the hospital has been at the forefront of orthopaedic care, pioneering new surgical techniques and advancing treatment for people with bone and joint disorders. That heritage of innovation and excellence still drives the Trust today continuing to push boundaries to deliver the best care possible. It is the aim to be the Trust to be the first choice for orthopaedic care.

1.1. The Department

The Department of Musculoskeletal Pathology falls in the Division 2 (Patient Support).

The Department of Musculoskeletal Pathology provides a specialised histology service to the Royal Orthopaedic Hospital NHS Foundation Trust including special stains, immunohistochemistry, "large" blocks and a FISH / RT-PCR molecular biology service. Information on the services provided and contact telephone numbers are available in a series of publications and on the hospital website. The Trust has information on its Policies and Procedures on the Trust Wide Intranet Service

The Department of Musculoskeletal Pathology comprises the histology laboratory, the molecular biology laboratory, reporting room, general office and other associated offices.

The Department of Musculoskeletal Pathology is part of The Royal Orthopaedic Hospital NHS Foundation Trust. The postal address is:-

Department of Musculoskeletal Pathology
(Royal Orthopaedic Hospital NHS Foundation Trust)
Robert Aitken Institute of Clinical Research
University of Birmingham
Vincent Drive
Edgbaston
Birmingham
B15 2TT

Tel 0121 414 7641
Fax 0121 414 7640

The postal address of the parent organisation is:-
The Royal Orthopaedic Hospital NHS Foundation Trust
Woodlands
Northfield
Birmingham
B31 2AP

Tel. 0121 685 4000
Fax 0121 685 4111

This Quality manual is split into two main sections; Section A deals with compliance with ISO15189 (UKAS) and Section B (Appendix A) with compliance with the HTA standards for research.

2. ISO 15189

This section of the Quality Manual describes the Quality Management System of the Department of Musculoskeletal Pathology. Throughout the text there are references to ISO15189 Standards (in brackets) and to procedures / policies **[indicated by square brackets],** written in fulfilment of these standards.

This Quality Manual **(4.2.2.2)** fulfils two functions. It describes the scope of the Quality Management System for the benefit of the laboratory's own management and staff, and it provides information for users and for inspection/accreditation bodies.

This Quality Manual can be regarded as the index volume to separate volumes of management, laboratory, clinical and quality procedures. The sections of the Quality Manual are arranged so that they equate with the ISO 15189 Standards. Under the title of each standard there is a brief description of the way in which the Pathology Department 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 9 describes the organisation of a laboratory and its quality management system, which uses resources (Sections 10, 11 and 12) to undertake pre examination, examination and post examination processes (Sections 13, 14 and 15). The quality management system and the examination processes are continually evaluated and quality assured (Section 16). The results feedback to maintain / improve the quality management process where required and to ensure that the needs and requirements of users are met.

3. Executive Summary

This policy specifies the approach to quality in the Department of Musculoskeletal Pathology, Royal Orthopaedic Hospital NHS Foundation Trust

3.1. Target Audience

- Staff working within The Organisation's Pathology Department.
- Users of the organisation's Histopathology services.

3.2. Implementation

The Department must:

- Display the Quality Policy in public areas of the laboratory.
- Regularly assess user satisfaction.
- Identify a member of staff in each area to take a lead in quality issues who will be responsible for accurate document and record maintenance.
- Ensure that each area partakes in and documents internal quality assurance activity.
- Ensure that each area belongs to and participates in appropriate External Quality Assurance schemes with evidence of performance review.
- Ensure that each area is routinely active in addressing Health & Safety, Staff training/development, appropriate equipment maintenance and internal audit.
- Ensure that the handling of all specimens facilitates the correct performance of laboratory examinations.
- Ensure that the reporting of results is timely, accurate and clinically useful.

3.3. Introduction

- The Quality Policy of the laboratory reflects the approach to Quality of The Royal Orthopaedic Hospital NHS Foundation Trust (The Organisation)
- The Department of Musculoskeletal Pathology is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users.
- Quality, continual improvement and user satisfaction are the personal responsibility of all Pathology staff.
- The ISO 15189 standard as assessed by the national pathology accrediting body, United Kingdom Accreditation Service (UKAS) and the Human Tissue Authority (HTA) requires the Directorate of Pathology to produce a Quality Policy.
- The Laboratory Department Management Group sets the Laboratory Quality Policy and objectives.
- In order to achieve Quality Improvement goals the laboratory's quality performance is continually reviewed

4. Statement of the Quality Policy

The scope of service provided by the Musculoskeletal Pathology Department is an in-house routine diagnostic service for Cellular Pathology (Histology) during core working hours in the day. The Musculoskeletal Pathology department does not provide mortuary and post mortem facilities.

The Musculoskeletal Pathology Department is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users. In order to ensure that the needs and requirements of users are met, the Pathology Directorate will:

- Operate a Quality management System to integrate the organisation, procedures, processes and resources.
- Set quality objectives and plans in order to implement this Quality Policy.
- Ensure that all personnel are familiar with this Quality Policy to ensure user satisfaction.
- Ensure that personnel are familiar with the contents of the Quality Manual and all procedures relevant to their work.
- Commit to the health, safety and welfare of its entire staff.
- Ensure that visitors to the department will be treated with respect and due consideration will be given to their safety while on site.
- Uphold professional values and be committed to good professional practice and conduct.
- To keep advised of and to implement, where applicable, all current legislation relating to the Health and Safety of staff and visitors.
- Commit to comply with all the relevant environmental legislation.
- Conform to confidentiality in accordance with The Data Protection Act and Caldicott Guidelines.
- Commit to the issuing of accurate results/reports in a time frame suitable to the requirements of users.
- Commit to continual quality improvement.
- Aim for zero complaints.

The Pathology laboratory will comply with the requirements of the ISO15189 standard for the scope of its practice as well as complying with the requirements of The Human Tissue Authority, ISO 22870 and is committed to:

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

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

Signed on behalf of the

Department of Musculoskeletal Pathology

Dr V P Sumathi

Acting Clinical lead Musculoskeletal Pathology

5. Aims and Objectives

The aim of the Musculoskeletal Pathology Department at The Royal Orthopaedic Hospital NHS Foundation Trust is to provide clinically useful information through the laboratory analysis of samples from patients, taking into account the requirements of the laboratory's users. The reported data should be reliable and their uncertainties should be in accordance with the clinical needs and the appropriate technical standards of the profession. Quality records will be maintained to document effective implementation of the Quality Management System and provide evidence of conformity to ISO15189 standards and other relevant regulatory requirements. When problems occur in a process, outputs, the Quality Management System or when user complaints are received, the appropriate corrective action is taken.

Responsibilities

- This policy must be communicated, understood, available and implemented throughout the laboratory
- All staff working within the Directorate of Pathology.

Further Information

- ISO 14050:2010
- ISO/DIS 9001:2008
- ISO/DIS 15189:2012
- EC4 Essential Criteria
- ISO/IEC DIS 17011:2004
- ISO 9000:2005
- ISO/IEC 17025:2005
- ISO 14001:2004

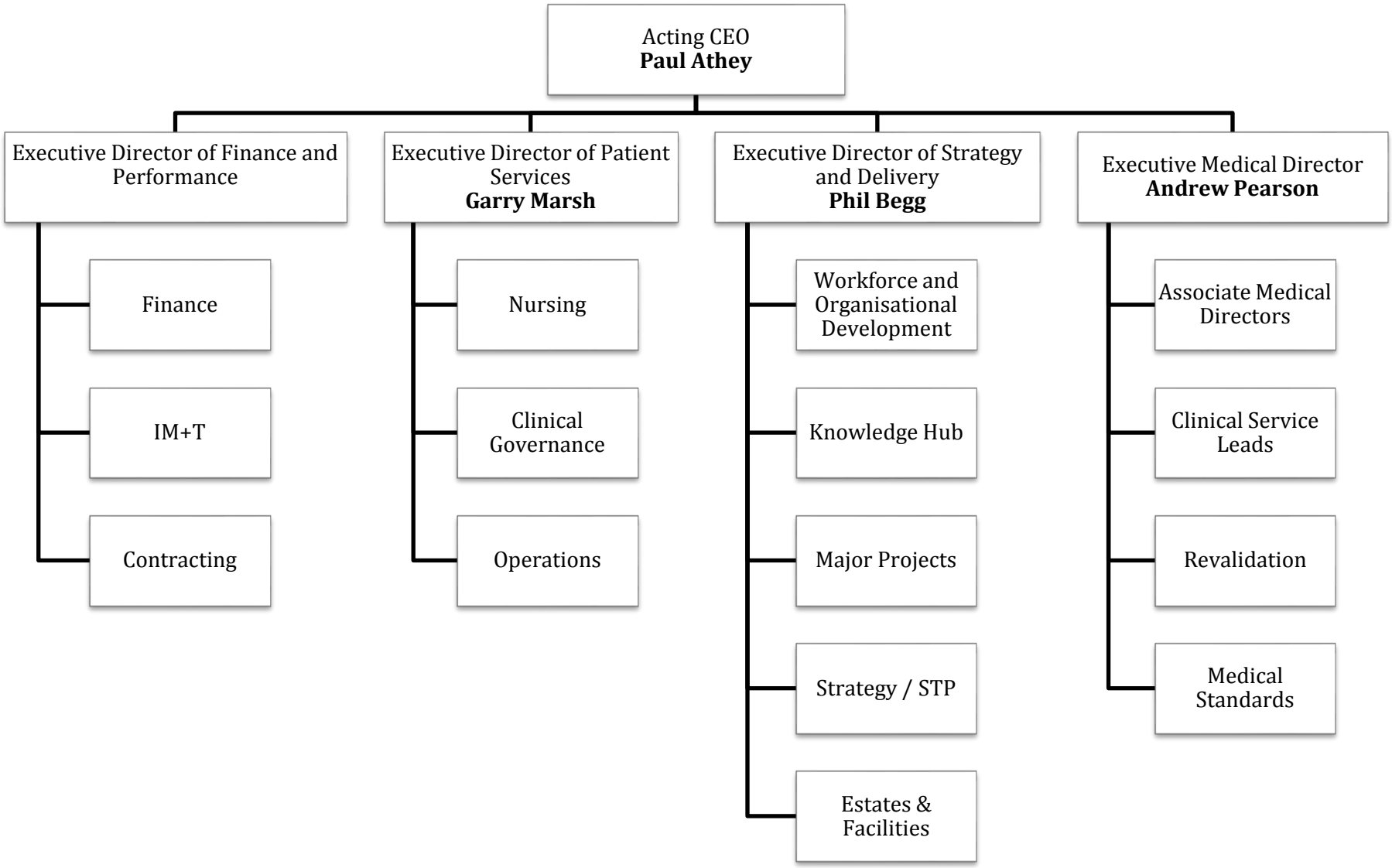
6. Relationship to external organisations

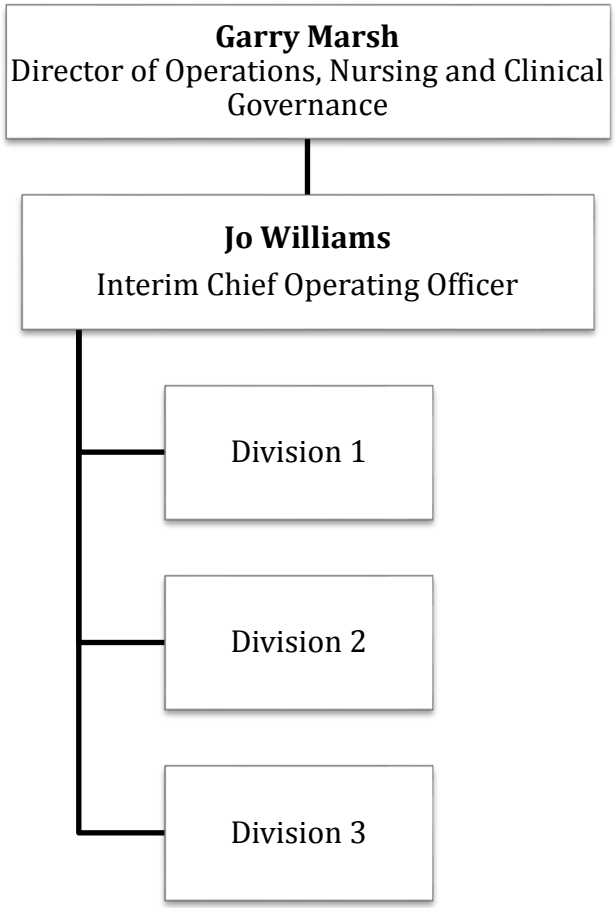
The Musculoskeletal Pathology Department forms part of the Patient Support Division (Division 2) within The Royal Orthopaedic Hospital NHS Foundation Trust

The Musculoskeletal Pathology Department is also associated with the following external organisations:

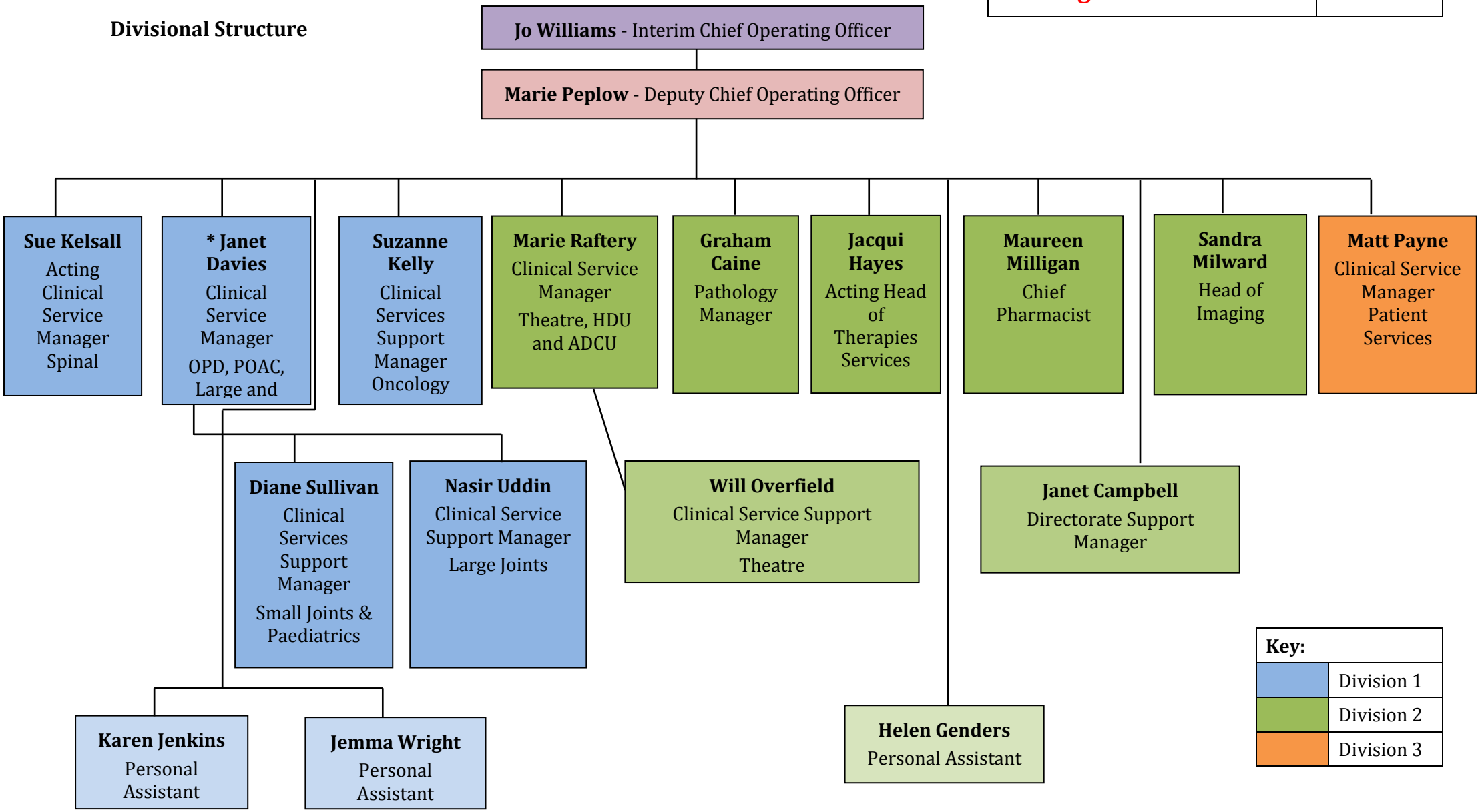
- Clinical Pathology Accreditation (UK) Ltd / United Kingdom Accreditation Service
- Human Tissue Authority
- United Kingdom National External Quality Assessment service
- Royal College of Pathologists CPD scheme
- Institute of Biomedical Sciences CPD scheme

6.1. Trust Structure

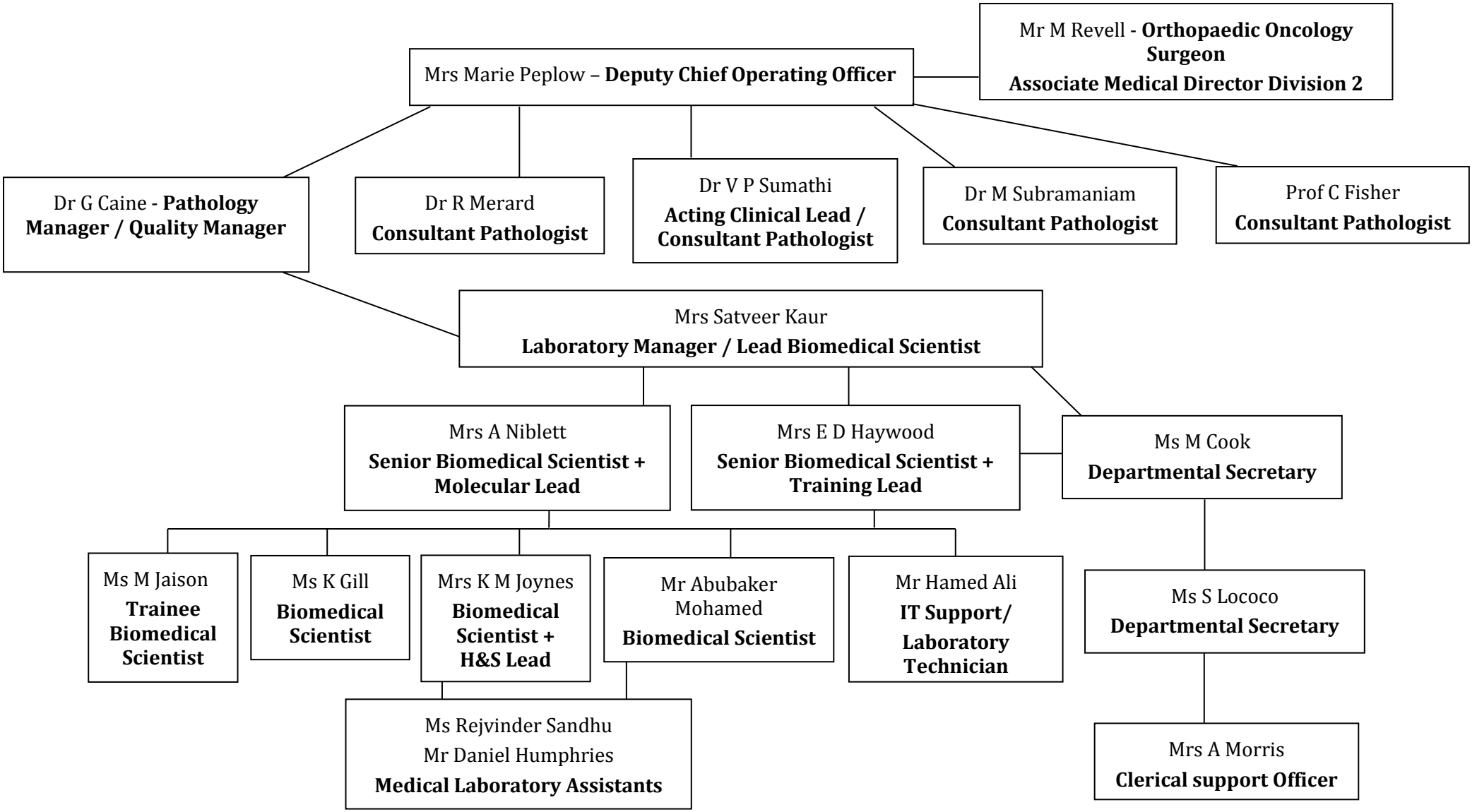



Garry Marsh
Director of Operations, Nursing and Clinical Governance
Jo Williams
Interim Chief Operating Officer
Division 1
Division 2
Division 3

Divisional Structure



Departmental Structure



The Interim Chief Operating Officer (Jo Williams) is accountable to The Director of Operations, Nursing and Clinical Governance (Garry Marsh) for clinical matters and non-clinical matters.

The Associate Medical Director is accountable to the Executive Medical Director. Both the associate director of operations and the associate medical director are responsible for directing the overall clinical, quality and financial performance of the Division. As a member of the Organisation's Executive Management Group, the Pathology Manager contributes to and shares responsibility for corporate strategy and the management and performance of the Organisation.

7. Relationships within the Musculoskeletal Pathology Department

The roles and responsibilities of laboratory management are:

7.1. Pathology Clinical Lead

Operational responsibilities for representing the medical workforce including the development and implementation of workforce plans, recruitment and retention plans, training and development plans, and (including both medical and non-medical staff) initiatives to improve workforce effectiveness, in order to continually improve the quality of agreed service levels. To assist, develop and agree future plans and strategies for the histopathology service. To agree levels and models of service delivery with the involvement of clinicians to form the basis of commissioning arrangements with clinical services to ensure the delivery of timely, clinically appropriate and effective services. To monitor performance against targets and objectives with the support of directorate management. To implement the pillars of clinical governance within the department of musculoskeletal pathology and provide analysis of performance thereof through the divisional structure, particularly managing risk and improving patient safety.

7.2. Pathology Manager

The Pathology Manager has organisation wide responsibility for the operational management and modernisation of Pathology services within the organisation. The Pathology Manager works with the Pathology Clinical Lead, the Divisional General Manager, Laboratory Manager and Team leads to develop and implement the planning and performance management agenda for Pathology across the organisation. The Pathology Manager provides operational management leadership to the Directorate including working with the Discipline Management (DM) Teams to ensure effective budget management & monitoring, workforce management & planning and ensuring effective use of resources and equipment. The DM plays a lead role in modernisation of the service in line with local and National strategies. This involves all aspects of the planning and preparation for the delivery of services in a Clinical Futures/Designed for Life framework.

7.3. Quality Manager

The Quality Manager ensures, on behalf of laboratory management, that the Directorate of Pathology's quality management system functions correctly and has a defined role for:

- Ensuring a quality management system is implemented and maintained.
- Reporting to laboratory management on the functioning and effectiveness of the quality management system.
- Coordinating the awareness of the needs and requirements of users.
- Acting as clinical governance lead on behalf of the Pathology Manager and clinical Lead.
- Acting as complaints coordinator for the Department.
- The quality and budgetary issues relevant to the Pathology the Royal Orthopaedic Hospital NHS Foundation Trust.

7.4. Laboratory Manager / Lead Biomedical Scientist

There is a Lead Biomedical Scientist for the Department of Musculoskeletal Pathology having responsibility for technical and quality issues. With the support of the Pathology Manager he/she provides strategic leadership and day to day operational management of the scientific and administration workforce within the department. The position has a lead role in managerial, educational, professional and technical issues within the department, in conjunction with the Clinical Head of Department. This includes:

- Responsibility for the technical development of the service in close collaboration with the Head of Department.
- Development and promotion of organisation-wide working and standardisation of operational policies, procedures and practices within the discipline and within the appropriate Pathology Directorate Management team.
- Working together with the Clinical Lead he/she provides team leadership for the organisation-wide discipline. This involves contributing to the Management Team to develop and implement the planning and performance management agenda for Pathology across the organisation.
- Taking a lead role in the implementation of new techniques and facilitate research and development in collaboration with the Clinical Lead and Pathology Manager.

7.5. Pathology Information Technology Lead

- To act as the lead for organisation-wide information technology and information management.
- To be responsible for the IT development of the service and direct the assessment of new software and hardware for the provision of effective IT solutions for the Musculoskeletal Pathology service.

- To produce timely and accurate management and performance information as required by Divisional General Manager, Pathology Manager, members of the Pathology Management Team and users of the service.

8. Meetings (4.1.2.6 & 4.13t)

8.1. Pathology Departmental Meetings

Departmental meetings are scheduled to meet at least four times per year open to all staff within the relevant department.

Function

- Discuss IQA and EQA performance
- Discuss departmental procedural / developmental issues
- Discuss departmental health & safety issues
- Discuss departmental equipment requirements
- Discuss departmental staffing issues
- Discuss Staff training issues
- Discuss Staff Suggestions
- Discuss the effectiveness of the Quality Management System and compliance with accreditation standards.
- Discuss/address laboratory based H&S issues
- Plan/act on H&S audits
- Review accidents / clinical incidents
- Review risk assessments
- Ensure that appropriate national education and training legislation and regulations are maintained.
- Discuss and provide direction to the process of staff education and training so that the demands of the service can be met.
- Monitor each discipline's training and education programme including CPD activity.
- Ensure that appropriate resources for staff training and education are available.

Membership

- Chairman – Laboratory Manager
- Clinical Lead
- Secretary
- All members of the department

Minutes

[Minutes associated with this document are found in the 'Minutes' section of the Quality Management System]

8.2. Quality Meetings

Function

- To review the Quality activity to gain an overview of Instigated quality improvement
- Level of compliance to CPA, MHRA, HTA Standards and other quality standards
- Audit activity
- User survey activity
- Quality Assurance performance
- Departmental error logging

Membership

Chairman – Laboratory Manager/Quality Manager

Quality Lead

Departmental area leads

IT lead

Minutes

[Minutes associated with this document – are found in the 'Minutes' section of the Quality Management System]

8.3. Senior Staff Meeting

Function

- To review any issues not covered by other meetings

Membership

- Pathology Manager
- Laboratory Manager
- Clinical Lead
- Divisional Manager (when required)

Minutes

[Minutes associated with this document – are found in the 'Minutes' section of the Quality Management System]

9. Management requirements

9.1. Organisation and management (4)

The organisation and management of the Department of Musculoskeletal Pathology is detailed under the section entitled "Organisation, Responsibilities and Authorities" in this quality manual.

9.2. Needs and requirements of users (4.1.2.2)

The needs of the users are kept under constant review. This is achieved by:

- Providing workload measurement to the Divisional Board and Trust Board when required.
- Both the Pathology Manager and Clinical Lead are members of the Divisional Board and attend board meetings where any issues regarding the Department and the needs of its users can be discussed.
- Provision of a Pathology handbook containing user guidelines.
- User satisfaction surveys.
- Maintenance and analysis of complaints / suggestions logs leading to change / improvements with quality of service delivered where necessary.
- MDT meetings

The needs of the users are translated into requirements, which form the focus of objective setting and planning **(4.1.2**.4) within the quality management system. Assessment of user satisfaction and complaints **(4.8)** is conducted on a regular basis and consideration of the findings form part of the annual management review **(4.12 & 4.15).**

9.3. Quality Policy (4.1.2.3)

The Quality policy of the Pathology Directorate is detailed on page **7** of this quality manual.

9.4. Quality Management System (4.2)

The components and relationship within the Quality Management System are described throughout this Quality Manual.

9.5. Quality objectives and plans (4.1.2.4)

The quality objectives for the Directorate are discussed, agreed and documented at the annual management review and the senior management team in Pathology. The Laboratory Management Team defines the quality objectives of the laboratory in consultation with the individual areas within the department and is responsible for ensuring that plans are made to meet these objectives.

The annual management review, determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans and the functioning of the Quality Management System. The quality objectives of

the department are documented in the Quality Improvement Plan in accordance with the department's Evaluation and Continual Improvement policy.

[MP27 Evaluation and Continual Improvement]

9.6. Quality Indicators

Quality indicators are established to monitor key aspects of the department which can compromise patient care. The departmental quality indicators are :

- Turnaround times – monitored monthly (audits on QMS)
- EQA results – monitored quarterly monthly (reported in the laboratory meetings)
- Number of CA/PA – monitored monthly (reported in the laboratory meetings)
- Audit completion – monitored quarterly monthly (reported in the laboratory meetings)

All indicators are reviewed annually at the AMR.

9.7. Quality manual (4.2.2.2)

This standard is fulfilled by the production of this Quality Manual.

[MP01 Quality Manual]

9.8. Quality manager (4.1.2.7)

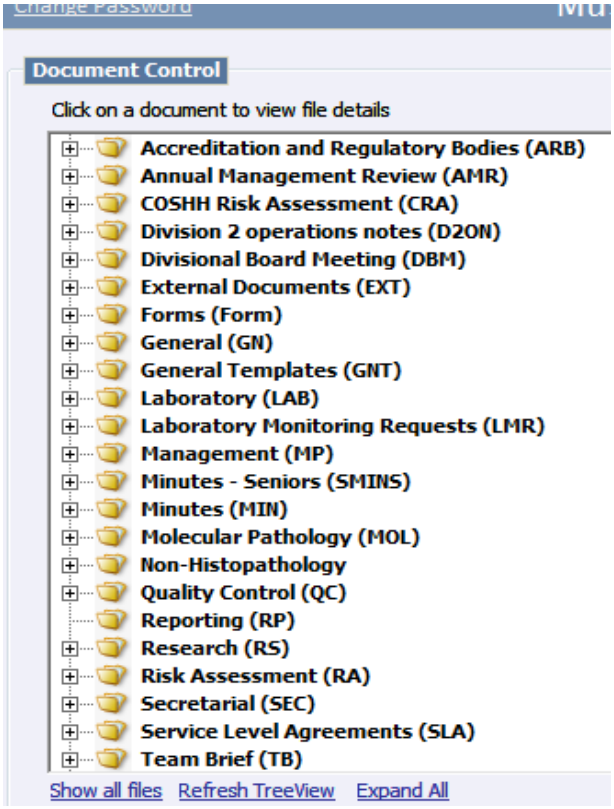
The Quality Manager for the Musculoskeletal Pathology Department works with the Departmental Senior Management Team to ensure the proper running of the Quality Management System.

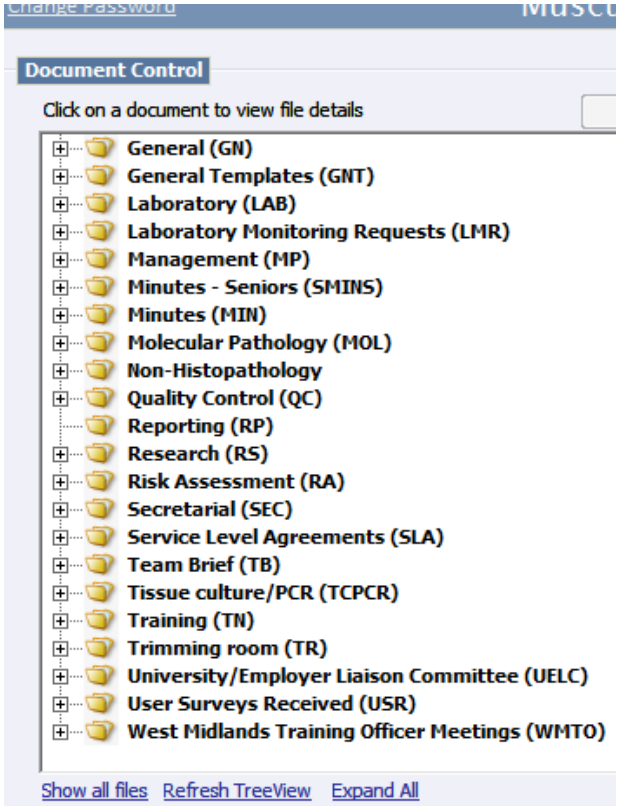
9.9. Document control (4.3)

The Department uses its own in house QMS as its procedure for document control.

[MP07 Document Control]

An outline of the structure of the documentation used in the quality management system **(4.2.2.2e)** is as follows:





- Health and Safety documents are under prefixes CRA and RA.
- Procedure related documents are split into different section of the laboratory. These are Laboratory, molecular pathology, trimming room and secretarial.
- All departmental policies are held under 'Management'.
- All training material used within the laboratory is kept within the training folder.
- Meeting minutes are held under the types of meeting they are e.g. seniors, divisional board, training officer etc.

9.10. External services and supplies (4.6)

The Pathology Department has documented procedures for the selection and purchasing of external services including that for equipment, reagents and consumables that relevant to the quality of scope of service.

[MP03 Laboratory Equipment, Services, Reagents and Consumables Policy and Procedure and MP26 External Services Agreement Policy and Procedure]

9.11. Service Level Agreements (4.4)

Service level agreements are setup by the department for any external customers or suppliers of tests. FROM111 is used as a checklist to ensure all aspects of the agreement are covered. Service level agreements are reviewed quarterly, with an annual review taking place at the end of the year (FORM112).

[MP26 Services Agreement Policy and Procedure]

9.12. Control of process and quality records (4.13)

The Department has an established procedure for controlling process records and quality records in accordance with the Department's policy "Retention and Storage of Pathological Samples and Archives in the pathology department.

[MP08 Control of Process and Quality Records]

This procedure includes:

A. Identification and indexing.
B. Security.
C. Retention.
D. Storage and retrieval.
E. Disposal.

9.13. Control of clinical material (5.4.6, 5.4.7, 5.7.2 & 5.7.3)

Laboratory management have established procedures for controlling clinical material

[MP09 Control of Clinical material]

9.14. Management review (4.12 & 4.15)

The Laboratory management participates in an annual service review which provides a mechanism to review the following items:

- User satisfaction surveys and complaints
- Clinical incidents and near misses
- Laboratory and clinical audit
- National benchmarking data
- Internal and external quality assurance

The Laboratory management team within the department conducts an annual review, the content of which is detailed in the Directorate's annual management review policy:

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

10. Personnel

10.1. Professional direction (4.1.1.4)

A. Dr Sumathi {Pathology Clinical Lead} professionally leads the clinical direction of the department.
B. Dr Graham Caine (Pathology manager) is the head of the department and is supported by the Ms Satveer Kaur (Laboratory manager) who is the lead biomedical scientist.

10.2. Staffing (5.1)

Staff records are available from the Laboratory Manager or Pathology Manager within the department or the Divisional Manager as appropriate. Hard copy staff records are held locally by the Laboratory manager and some records are held on the Organisation's Electronic Staff Record (ESR).

The Departmental Lead Biomedical Scientist holds appropriate professional qualifications and works closely with Clinical lead, Pathology manager and divisional manager.

The Pathology Manager and Laboratory Manager ensure that there are appropriate numbers of staff, with the required education and training to meet the demands of the service and appropriate national legislation/regulations **(5.1.2).** Registration of staff is in accordance with current national legislation and regulations.

Staffing includes one or more individuals with the following roles **(4.1.2.5):**

A. Pathology Manager / Quality Manager (Dr Graham Caine) **(4.1.2.1f & 4.1.2.7)**
B. Laboratory Manager / Cellular Pathology Quality Lead (Satveer Kaur)
C. Area Leads
    a. Main Laboratory and Immunohistochemistry (Mrs Elaine Haywood)
    b. Molecular Laboratory (Mrs Angela Niblett)
    c. Trimming Room (Kulvinder Gill)
    d. Research (Mrs Karen Joynes)
    e. IT Support (Mr Hamed Ali)
    f. Health and Safety Officer (Mrs Karen Joynes)
    g. First Aiders (Ms Kulvinder Gill, Mr Hamed Ali)
    h. Office (Ms Marion Cook)

10.3. Personnel management (5.1.1)

The Division has a Human Resources Manager (Ms Navdeep Dhillon) and a Human Resources Assistant Mrs Aruna Venkatachalam, assigned by the organisation, to assist with personnel issues. The Division and department comply with all Human Resources policies laid down by the organisation. The organisation reviews these policies regularly and the Division and department can contribute and influence these policies. All Personnel draft policies are also distributed widely throughout the organisation for consultation before being implemented. The Trust through the Organisation's Personnel department has procedures for:

a) Staff Orientation and Induction **(5.1.4)**

The general staff induction policy is accessed via the organisation's Intranet. Local guidelines for specific induction issues within the department not covered in the induction manual can be found in

[GN05 Staff Induction]

All new staff are instructed to attend an organisation induction day which is additional to local induction within the Pathology Department. Induction records are filed in individual personal records and on ESR which are held in the Pathology Manager / Laboratory Manager's office.

[ROH Trust Corporate and Local Induction Policy]

b) Job description and contracts **(5.1.3)**

All staff job descriptions should be produced using the Trust's agreed format in accordance with its policy:

[MP02 Personnel Management and ROH Trust Recruitment Policy]

These are reviewed annually at appraisal and records are kept in individual personal records. All staff are issued with a contract of employment on entering service and copies are kept in the personal records held by the Lead Biomedical Scientist of the department.

c) Personal Appraisal Development Review (PADR) **(5.1.7)**

There is a Trust policy on annual PADR which is followed by the Department. Refer to "**PERFORMANCE AND DEVELOPMENT REVIEW'** which is on the intranet.

Laboratory management ensures that all staff in the Director participates in PADRs in accordance with the Trust's policy:

[MP02 Personnel management and ROH Trust Performance Development Review Policy]

All staff performing PADRs have received appropriate training and all staff participating have full explanation of the process **(5.1.7 note)**.

The Department operates a cascade system of appraisal, individuals being appraised by the next manager or scientist in line above the appraise. The standard Trust's documentation is used at these meetings.

d) Personal files and staff records **(5.1.9)**

Each member of staff has a local personal hard copy file as well as an electronic staff record on ESR. All staff records are confidential and abide by the Trust's guidelines and national legislation. Staff records include information in accordance with the Department's policy on staff records:

[MP02 Personnel management]

e) Staff meetings and communication **(4.1.2.6)**

There are regular departmental meetings open to all staff providing the opportunity for exchange of information including staff suggestions. Minutes of these meetings are kept and made available to staff.

Communications between the organisation and the Directorate are maintained by the following mechanisms:

- Chief Executives report.
- The organisation Intranet. [Royal Orthopaedic Hospital NHS Foundation Trust]
- E-mail.
- Organisation Health and Safety Committee
- Health Board Quality and Patient Safety Operational Group
- Staff suggestions

Local communications between the Directorate and all departments are made through regular, Directorate and staff meetings.

f) Staff training and education **(5.1.5 & 5.1.8)**

Staff have access to education and training commensurate with their needs and position in the organisation. Training plans are identified at annual PADR and feed into an individual's personal development plan. All BMS training staff are supported by a designated mentor within the department and follow the guidelines set out in the Institute of Biomedical Sciences training portfolio. All trainee staff have a designated supervisor and are supervised at all times during their training. The Directorate has dedicated resources to provide education and continual professional development for training and trained staff. There are comprehensive library facilities within the organisation, and staff have access to the Internet for scientific information, a quiet room for private study, attendance at meetings and conferences and financial support. Training records are kept in personal files within the departments **(5.1.9).** CPD activities of the BMS staff and Consultant staff are maintained individually. The effectiveness of training programmes are periodically reviewed. There is a mechanism in place for ongoing assessment of staff competency **(5.1.6)**.

The department has an Education and Training Officer who ensures that there is training and education programme for all members of staff which:

- Is in accordance with guidelines from the relevant professional and registration bodies.
- Provides the opportunity for further education and training in relation to the needs of the service and their professional development.
- Includes the following areas **(5.1.5)**:
  a) The quality management system
  b) Assigned work processes and procedures
  c) The laboratory information system
  d) Health and safety, including the prevention or containment of the effects of adverse incidents.
  e) Ethics and confidentiality of patient information.

Personnel undergoing training are supervised as appropriate at all times during their training period.

11. Accommodation and environmental conditions (5.2)

The laboratory provides accommodation and conditions for staff conducive to the proper performance of their respective duties in accordance with the Pathology Premises and Environment Policy

[MP06 Health and Safety]

11.1. Health and safety (5.2.1)

It is the Department's policy to provide and maintain a healthy and safe working environment for all our employees and visitors to the laboratory. The term "visitors" includes staff of the organisation undertaking their normal duties, those delivering goods, contractors, company representatives, other visiting professional groups, patients bringing samples, having samples taken or visiting Consultants.

The Department complies with the Trust's Health and Safety policy and also has its own Health and Safety Policy.

[MP06 Health and Safety and ROH Trust H S policy]

Staff are made aware of their responsibilities for Health and Safety **(5.1.5d)** in:

- Contract of employment.
- Induction training **(5.1.4)**.

- Job descriptions.

The Department has health and safety procedures in each area that cover:

- Action in the event of fire.
- Risk assessment and reporting.
- Disinfection.
- Decontamination of equipment.
- COSHH and chemical handling.
- Storage and disposal of waste.
- Specimen collection handling.
- Incident reporting.

Laboratory containment facilities conform to the requirements of the ACDP guidelines on the containment of hazardous pathogens and agents and regulations on radioactivity.

The department will:

- Provide and maintain healthy and safe working conditions in accordance with the statutory requirements.
- Provide safety training as part of job induction together with special training where appropriate. Records will be kept of training.
- Provide safety equipment, protective devices and protective clothing as necessary and will ensure that they are used in an appropriate manner.
- Investigate all accidents and possible health hazards, taking appropriate action where necessary.
- Set an example of safe behaviour in all activities.
- Stimulate an interest among all our staff in all aspects of safe working practices and procedures.
- Ensure risk assessments are undertaken and necessary actions are taken to establish safe and proper working practice.
- When instrumentation or methodology is changed ensure that the risk assessments are updated.
- Ensure visitors are escorted at all times.
- Ensure in the event of evacuation, visitors are under the care of a member of staff.
- In the event of illness visitors are seen by a member of the laboratory's First Aid or Medical staff and if need be, referred to the A & E department via the ambulance service.
- If any accidents or incidents occur, they are reported and fully investigated.

The department is subject to local Health and Safety inspection/audit managed by the laboratory Health and Safety representative. Inspection includes standards of cleanliness and housekeeping.

The Organisation provides occupational health facilities for staff. It is the policy of the department for staff to have free access to these facilities.

Occupational health services are provided by Heart of England NHS Foundation Trust.

12. Laboratory equipment, reagents and consumables (5.3)

12.1. Management of Equipment (5.3.2.1).

The Department has a programme for the replacement of equipment detailed in an annual plan that identifies the new and replacement equipment requirements, ensuring quality and capacity is addressed.

[MP03 Procurement and Management of Equipment.]

The Department complies with national guidelines and the organisation policy on purchase, installation, training and safe disposal of all equipment.

The Department complies with the organisation's policy for Standing Orders, Tendering and Contract Procedures, Standing Financial Instructions which includes compliance with national legislation for:

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

[ROH Trust Procurement Policy]

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

An inventory of equipment (5.3.1.7) is held by the department on the QMS under 'Assets' and includes:

- The asset number of equipment (over £5k in value).
- The identity of the equipment
- Location of the equipment
- Serial number.
- Date of purchase, date of entering into service and disposal.
- Condition when received (new, used or reconditioned)

- Contact details for the supplier or manufacturer
- Manufacturer's instructions
- Verification records for when equipment is incorporated into the laboratory
- Equipment performance records confirming equipment's ongoing acceptability for use
- Record of maintenance.
- Damage to, malfunction, modification or repair of the equipment
- Electrical safety checks are carried out on a regular basis by the organisation's maintenance staff and all equipment is marked, identifying the last inspection date and when the next inspection is due.
- Where appropriate, equipment shall be regularly maintained by hospital engineers or through a maintenance contract with outside engineers.
- Where it is necessary for new equipment to be commissioned and/or calibrated prior to use, this shall be carried out either in-house or through the relevant body as appropriate.
- Manufacturer's operating and maintenance manuals are held in the relevant section of the laboratory. Where necessary the manufacturer's manuals are supplemented by documented in-house methods with information pertaining to the operation, maintenance and calibration of such equipment.
- These can be found within procedure manuals located within the individual departments.
- Maintenance records for equipment on service contracts are held on the QMS as are records and certificates pertaining to the calibration of equipment.

12.2. Management of data and information (5.10)

Data and information is controlled and managed within the Department under the guidance of the organisation finance and information service. The Department operates in accordance with the organisation's control measures for:

- Data Security

  [MP10 Management of Data and Information and ROH Trust Information Security and Confidentiality Policy]

- Electronic passage for data to remote user.

  [ROH Trust Information Security and Confidentiality Policy]

- Storage, archive and retrieval of records.

  [MP10 Management of Data and Information and ROH Trust Records Management Policy]

- Safe disposal.

[MP10 Management of Data and Information and ROH Trust Records Management Policy]

- Access to electronic data is controlled and restricted through individual password security and assigned privilege rights **(5.10.2)**. All electronic data is backed up by the organisation's IT department and stored in a remote location to the Department.

[MP10 Management of Data and Information and ROH Trust Records Management Policy]

The Directorate complies with current national legislation and regulations in relation to data protection including The Freedom of Information Act and Caldicott guidelines **(5.10.3c)**.

12.3. Management of laboratory equipment, reagents and consumables (5.3)

The Department ensures the funding and availability of adequate and suitable materials required for providing a quality service to users **(5.3.2)**. The Department operates in accordance with the organisation's financial procedures for:

- The selection, purchasing and ordering of materials.
- Assessment of suitability of materials (acceptance testing).
- Receipt of goods.
- Safe storage and issue of records.
- Safe disposal.

[ROH Trust Procurement Strategy]

Commercial kits should be CE marked and manufacturers' instructions followed. Any changes should be fully validated and standardised.

Materials in use are identified with date of receipt, date of first use, lot numbers and expiry dates **(5.3.2.7)**.

Additional information also includes identity of reagent, manufacturer name, contact information of supplier, condition when received and manufacturer instructions where appropriate.

Reagents and chemicals in use are COSHH assessed in accordance with organisational guidance.

[ROH Trust COSHH Policy and Department Quality Management System 'COSHH' section– CRA database]

13. Pre-Examination Processes (5.4)

13.1. Information for users and patients (5.4.2)

Information for users of the service is available in the pathology user's handbook, which is updated regularly. Information to users includes all information reasonably required to access and use the laboratory effectively.

Available patient information leaflets include:

- An explanation of any preparation required before attending **(5.4.2g)**.
- An explanation of the procedure.
- The expected duration time of the investigation **(5.4.2d)**.
- Request form **(5.4.3)**
  The Request form is designed to provide all relevant information required to provide a safe and meaningful report including clinical advice and to satisfy internal audit requirements.
- Specimen collection and handling **(5.4.4)**.

There are departmental procedures laid down for specimen collection and handling.

[MP28 Specimen Transport]

The guidelines for which are given to service users in the user manual.

[MP11 User Manual / Operational Policy]

13.2. Specimen transportation (5.4.5)

Arrangements are made for Non Patient Transport Services to collect the samples and deliver them to the laboratory.

Specimens in the pre-filled 60-ml pots should be transported in plastic transport bags with their accompanying request form. The sender must ensure that the specimen containers are tightly capped and will not leak fixative during transportation. Multiple specimens must be transported to the department in proper sealed specimen containers, which comply with rules of health and safety. Larger volume specimens sent to the department from the hospital theatres must be transported in proper contained specimen carriers which comply with health and safety rules. The specimen carrier must be properly sealed and leak proof so that the contents do not escape during transport.

The request forms accompanying the specimens must not become contaminated in any way.

[MP11- User Manual / Operational Policy and MP28 Specimen Transport]

13.3. Specimen reception (5.4.6)

The department has procedures to ensure:

- Specimens and requests are accurately identified and matched.
- Test requirements are accurately booked into the IT system.
- Account is taken of urgency.
- Documented monitoring of sample arrival times against the time samples are registered on the LIMS.
- Urgent Specimens **(5.4.6f)** - It is the policy of the Department to process all urgent specimens as soon as they arrive in the laboratory. These specimens shall take priority and will be processed and reported upon as soon as possible. There are also specific departmental policies relating to telephoning results where necessary. Turnaround time for urgent requests depends on a number of limiting factors. It is advisable for the requesting clinician to telephone the department for information regarding turnaround times for urgent histology requests.

If at any time the suitability of the sample for testing is in doubt, or where the sample does not conform to the description provided, a senior member of staff shall consult with the user for further instructions, before proceeding.

The department has criteria for rejection of samples, the recording of rejected samples and notification to the user of rejected samples **(5.4.6b)**.

13.4. Referrals to Other Laboratories (4.5)

The department makes every effort to use other laboratory services that meet ISO 15189 requirements or are CPA accredited during the transition period to ISO 15189 requirements. There are procedures for:

- Recording the tests referred.
- Documenting in the database, the results of referrals.
- A record of all laboratories used in the referral of samples.

[GN04 Details of Referral Laboratories]

The department periodically reviews the accreditation status of the laboratories they routinely refer samples for analysis, their EQA performance and periodically monitor turnaround times to ensure that requirements continue to be met.

14. Examination Processes (5.5)

The Department of Musculoskeletal Pathology selects and validates its examination procedures in accordance with its policy for examination processes.

14.1. Selection and validation of examination procedures

The range of examinations offered by the department is designed to meet the R.C.Path reporting guidelines, to ensure that a first class service is offered to our users.

The range of techniques available is constantly reviewed by the department and in consultation at MDT meetings.

Participation in MDTs and audit, peer review, participation in appropriate UK NEQAS schemes all assist in validation of examination procedures.

14.2. Measurement of Uncertainty

The Department, in common with other cellular pathology laboratories, uses little analytical equipment and reports few critical values but seeks to:

- Consider which reported measured values are clinically critical (rather than descriptive) and hence require consideration of the uncertainty of measurement to be available to users and UKAS assessors on request.
- Assess regularly that the use of the equipment achieves the desired objectives.
- Ensure that equipment used is calibrated regularly to a traceable standard (either by calibration laboratories that have been assessed and accredited by UKAS or by performing in-house calibrations, which can then be assessed by UKAS (to ISO/IEC 17025) as part of their assessment to ISO 15189.
- Maintaining process records of this activity in a secure location for assessment.
- Work to ensure that the measurement procedures are consistent between Pathologists by the use of reporting SOP's.
- Consider which are the best methods to achieve clinically reliable measurements and ensure these are defined in departmental SOPs.

14.3. Examination procedures

All examination procedures used within the department have an associated SOP. These documents detail the method to be followed, reagents/materials required, quality control, H & S etc. Copies of SOPs are located on the Departmental Intranet, no paper copies are kept.

14.4. Assuring the quality of examinations

Where appropriate all examination procedures include analysis of internal quality control material / procedures.

The monitoring of performance using External Quality Control schemes is carried out in laboratory meetings and in senior staff meetings.

Internal quality control is reviewed constantly as outlined in **[LAB07 Current Controls in Use and MP05 Evaluation and Quality Assurance]**

The department records any problems relating to any non - clinical incidents on the error log of the QMS with escalation to the Incident Reporting system (Ulysses) as appropriate.

These are reviewed by the Senior BMS staff and a report is given at the Department meetings. Areas for concern are discussed and a change of working practices reviewed as required.

15. Post Examination Processes (5.7)

15.1. Reporting results (5.8, 5.9)

The Department has written procedures for reporting results, which include:

- The report **[LAB08 Post Examination Procedures]**
- Telephoned reports **[LAB11 Disclosing Pathology Reports over the Telephone]**
- Amended reports **[LAB08 Post Examination Procedures]**
- Clinical advice and interpretation **[MP11 User Manual / Operational Policy]**

15.2. Clinical advice and interpretation (4.7)

The Department ensures that advice on investigations and the interpretation of reports meets the needs of the users and patients. The Department ensures that users have access to laboratory advice at all times. The Department ensures that all comments are clear, succinct, unambiguous and relevant to the user in the treatment of the patient.

The Department ensures that there is systematic communication between laboratory staff and clinical staff to promote effective utilisation of laboratory services and to consult on scientific and logistic matters. Where appropriate, records are kept of such meetings.

Clinical comments and advice is given only by suitably qualified medical or scientific staff in accordance with the Department's policy

16. Evaluation and audits (4.14)

16.1. Evaluation and improvement processes (4.12)

Ongoing evaluation and improvement processes are essential to ensure that the service provided by the Directorate meets the needs and requirements of our users. All Pathology staff is encouraged to make suggestions for the improvement of any aspects of the Pathology service. Recording, analysis and interpretation of this evaluation data are important parts of the Department's management process and as such form part of discipline annual management reviews in addition to feeding back to staff any actions taken in response to their suggestions **(4.14.4)**.

16.2. Assessment of user satisfaction and complaints (4.14.3)

The Department is committed to assessing user satisfaction and monitoring complaints so that the service provided by the laboratory meets the needs and requirements of users. This is achieved by listening to and seeking information from users of the service through:

- User questionnaires.
- Meetings with users, both internal and external to the Organisation.
- Resolving and monitoring user complaints.

The Department has a procedure for assessment of user satisfaction detailed in the Pathology Evaluation and Continual Improvement policy and complaints guidance:

[MP27 Evaluation and Continual Improvement Policy]

A record is maintained of any such complaints or anomalies and of any actions taken by the laboratory.

The Department strives to meet performance targets such as turnaround times in all areas **(4.14.7)**.

The Department assesses the clinical relevance of laboratory investigations performed and the reliability of interpretative reports in conjunction with its users **(4.14.2)**.

The Department participates in the evaluation of clinical effectiveness, audit and risk management activities of the Organisation and relevant external bodies **(4.14.5, 4.14.6 & 4.14.8)**.

16.3. Internal audit of quality management systems (4.14.5)

The Department uses internal audit to provide evidence that the quality management system is effective, implemented and maintained across the Department. The Department's audit process is detailed in the "policy and procedures for Internal Quality Management System Audits".

[MP27 Evaluation and Continual Improvement and GN30 The Production of Internal Audits]

16.4. Internal audit of examination process (4.14.5)

Each area within Pathology operates in accordance with the Department's policy for examination processes and audit their compliance to the requirements of this policy using the appropriate audit form.

[MP27 Evaluation and Continual Improvement and GN30 The Production of Internal Audits]

16.5. External quality assessment (5.6.3.1)

Each area within Pathology participates in approved external quality assessment schemes appropriate to the examinations and interpretations provided. Records of performance in these schemes are maintained reviewed and communicated to staff **(5.6.3.4)**. Where decisions are taken by disciplines in relation to their performance, these are recorded, monitored and acted upon. In instances where an appropriate external quality assessment scheme does not exist and no other formal inter-laboratory comparison programme is available, disciplines develop a mechanism for determining the acceptability of these procedures which are not otherwise externally evaluated **(5.6.3.2)**

16.6. Quality Improvement (4.12)

The department will strive to continually improve the quality of the service it provides. Quality improvement will be achieved by a number of processes that together should identify any potential risks, develop and implement corrective or preventative action plans and monitor effectiveness of these plans. Training and education of staff is vital to the successful implementation of any developments, and all staff are encouraged to participate in the appropriate Continual Professional Development Schemes. Service plans are produced annually to highlight areas for service/technical development. These are reviewed at the senior staff meetings and areas of achievement are recorded.

The service plans also identify to the Royal Orthopaedic Hospital NHS Trust Management Team the areas for development so that measures for their successful implementation can be put into place.

[MP20 Policy for corrective and preventative actions]

16.7. Identification and control of non-conformities (4.9)

Procedures are in place that ensures any nonconformity is effectively managed to minimise any risks.

17. Appendix A HTA Activities

The department has a number of research activities including tumour banking and these are regulated by the Human Tissue Authority

17.1. HTA Licence

The HTA licence of the Department of Musculoskeletal Pathology is a satellite of the Human application licence for The Royal Orthopaedic Hospital NHS Foundation Trust and published as a separate controlled document to be displayed within department

The HTA licence number is 12379

17.2. Purpose

The purpose of this section of the Quality Manual is to document the Department's Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human samples for research to ensure that all staff understand the necessary requirements and procedures covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Good Practice and the Trust's HTA licence for research activities under the licence for Human Application.

The successful implementation of the QMS framework of policies and procedures will ensure that all research involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA.

It is important that the research community and the public have confidence that all human samples for research are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly. The Trust requires that all human samples, acquired from the patients, cellular or acellular, or whether the material is classed as relevant or not under the HT Act, will be treated the same and that research using any human material should meet the same standards of quality management as set out in this Quality Manual.

The key quality objectives are to establish an effective QMS that will:

- continue to evolve to demonstrate an enduring commitment to quality improvement;

- provide a robust but practical framework for compliance with the licensing obligations of the HT Act and to the standards required by the HTA;
- be an integral component of the University's research governance framework;
- have the confidence of and be fully embedded into practice by all researchers;
- engender the highest levels of trust and confidence in our stakeholders and the broader public.
- Enhance the Trust's reputation for the delivery of research of the highest quality and ethical standards.

17.3. Human Tissue Act 2004 (HT Act)

The purpose of the HT Act is to provide a consistent legislative framework for issues relating to collection, storage, use and disposal of human tissue (including organs and whole bodies). It applies to England, Wales and Northern Ireland. There is separate legislation in Scotland (Human Tissue

Act (Scotland) 2006).

The HT Act allowed for the establishment of the HTA in April 2005 as the regulatory and licensing authority and enabled licences to be issued to organisations storing tissue for human application (i.e. the use of human tissue to treat patients, for example, transplantation) from April 2006 and licences for all other activities (i.e. scheduled purposes, such as research) from September 2006.

The HT Act makes consent the fundamental principle underpinning the lawful storage and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display (Scheduled Purposes). It also covers the removal of such material from the deceased.

The HT Act regulates the removal, storage and use of human tissue – defined as material that has come from the human body and consists of, or includes, human cells (Relevant Material). Cell lines that have divided outside the human body are excluded, as is hair and nail from the living.

Live gametes and embryos are also excluded as they are covered by regulation under the Human Fertilisation and Embryology Act 1990.

Offences under the HT Act, with penalties ranging from a fine to up to three years' imprisonment, or both, include:

- removing, storing or using human tissue for Scheduled Purposes without appropriate consent;

- storing or using human tissue donated for a Scheduled Purpose for another purpose;
- trafficking in human tissue for transplantation purposes;
- carrying out licensable activities without holding a licence from the HTA;
- having human tissue, including hair, nail and gametes (i.e. cells connected with sexual reproduction), with the intention of its DNA being analysed, without the consent of the person from whom the tissue came or of those close to them if they have died. Medical diagnosis and treatment, criminal investigations, etc. are excluded.

References

- http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm
- http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1

17.4. Human Tissue Authority (HTA)

The Human Tissue Authority (HTA) is an independent regulator, established by the Human Tissue Act 2004 (the HT Act) to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent.

The HTA licenses and inspects organisations that store and use human tissue for the following activities (Scheduled Purposes under the HT Act, for which consent from the donor is required):

- teaching about or studying the human body;
- carrying out post-mortem examination;
- using human tissue to treat patients;
- carrying out research on human tissue;
- displaying human bodies or tissue in public (e.g. in a museum).

The HTA aims to:

- make sure that these laws are followed by setting clear and reasonable standards;
- provide codes of practice and other advice, guidance and support (including the provision of workshops and e-learning packages);
- give the public confidence that their wishes when donating tissue will be respected, that their donated tissue will be put to the best possible use, and in turn increase the willingness of the public to donate;
- give the professionals confidence that they are working within a clear and effective regulatory framework for the removal, retention, use and disposal of that donated tissue.

17.5. HTA Licensing

An HTA licence is granted to an organisation if it shows it will comply with certain essential standards set by the HTA. When an organisation applies for a licence it assesses itself against those HTA standards. The HTA then evaluates the information provided and where necessary asks for more information before it issues a licence (Phase 1 Inspection). The HTA also inspects organisations to check that they maintain good standards and follow appropriate procedures (Phase 2 Site Inspection). Organisations the HTA consider to be highest risk are amongst the first to be inspected. (By law, organisations licensed by the HTA for human application are inspected every two years, for example).

Each licensed organisation has to nominate a person who will supervise the activities being carried out - the Designated Individual (DI). DIs undergo specific training provided by the HTA to undertake this role and have statutory duties as set out in the HT Act (Section 18).

A licence is granted for a principle activity or 'scheduled A licence is granted for a principle activity or 'scheduled purpose', such as research, and specifies the premises where the activity is to be carried out (where there may be multiple places where the activity is undertaken, but within the same organisation, the licence will specify a hub site and other satellite sites, where these different premises have separate postcodes).

The HTA grants licences in six key areas of activity (sectors):

- Human Application;
- Post Mortem;
- Anatomy;
- Research;
- Public Display
- Organ donation and transplantation

A licence is granted under certain conditions:

- Statutory (e.g. licensed activities must only take place on the premises specified in the licence; licensed organisations must ensure activities carried out under the licence are supervised; information required by the HTA is recorded and access to it is given to HTA inspectors as required; licence fees are paid to the HTA);
- Standard
- Additional (require compliance where a standard is not being met; to support the improvement of standards).

The HTA can revoke, vary or suspend a licence where, for example:

- Information in the licence application is found to be false or misleading;
- DI has failed to discharge their duties;
- Premises are no longer suitable.

The DI carries out the main responsibilities under the licence. The DI needs to ensure that suitable people carry out the activity using suitable procedures (and Standard Operating Procedures need to be available for these) and that any conditions attached to the licence are met.

17.6. HTA's Codes of Practice

Nine Codes of Practice provide guidance and lay down expected standards for each of the five sectors regulated by the HTA. The Codes are designed to support professionals by giving advice and guidance based on real-life experience, and were approved by Parliament in July 2009:

1. **Consent**;
2. Donation of solid organs for transplantation;
3. Post-mortem examination;
4. Anatomical examination;
5. **Disposal of human tissue**;
6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation;
7. Public display;
8. **Import and export of human bodies, body parts and tissue**;
9. **Research**.

The four key Codes for staff undertaking research are highlighted in **bold**

References

HTA's Codes of Practice:

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

17.7. HTA Standards

In order to obtain an HTA licence, an organisation must demonstrate that it meets a number of core standards. These relate to consent provision of the HT Act and the regulatory requirements for governance and quality systems, suitable premises and appropriate arrangements for disposal. These four core standards can be summarised as follows:

- Consent – *must be obtained as set out in the HTA Code of Practice 1: Consent*

- Governance and Quality systems – *must have systems in place to ensure the provision of safe tissue of reliable quality*
- Premises, Facilities and Equipment – *must be suitable for the licensed activity undertaken*
- Disposal – *establishments should develop a clear and sensitive disposal Policy*

There are generic, give goals to be achieved and provide a basis for the assessment of compliance with the HT Act and the HTA's Codes of Practice.

The HTA expects compliance with all its standards, even if human tissue is to be held only for a short period of time or if only a few samples are held under the authority of a licence.

References

HTA's Code of Practice 9: Research, paragraphs 82 – 115 for the HTA standards:

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm?FaArea1=customwidgets.content_view_1&cit_id=766&cit_parent_cit_id=757

17.8. The Trust License

The Trust is licensed to store human tissue (Relevant Material) at the following sites (Licensed Premises):

Hub site:	Satellite site:
Royal Orthopaedic Hospital NHS FT Bristol Road South Northfield, Birmingham B31 2AP	Department of Musculoskeletal Pathology Robert Aitken Institute of Clinical Research University of Birmingham, B15 2TT

Licence Holder: Royal Orthopaedic Hospital NHS Foundation Trust

Named Individual Ms Jo Chambers, Chief Executive

Designated Individual: Mr Neil Rogers, Division 2 General Manager

Person Designated (hub): Ms Rachel Bradley Hitchin

Person Designated (satellite): Mrs Karen Joynes

The licence authorises the storage of relevant material has come from a human body for use for the following scheduled purposes:

- Determining the cause of death;

- Establishing after a person's death the efficacy of any drug or other treatment administered to him/her;
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
- Public display;
- Research in connection with disorders, or the functioning, of the human body;
- Clinical audit;
- Education or training relating to human health;
- Performance assessment;
- Public health monitoring;
- Quality assurance.

The licensed activity should be carried on only at the licensed premises specified above, and under the supervision of the Designated Individual.

A copy of the licence is displayed at both sites

17.9. Quality Management System

The Department's Quality Management System (QMS) relates to the governance of the acquisition, storage, use and disposal of human samples for research to ensure that all staff understand the necessary requirements and procedures covered by the HT Act, the Human Tissue Authority's (HTA)

The successful implementation of the QMS framework of policies and procedures will ensure that all tissue stored for research at the Department involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA.

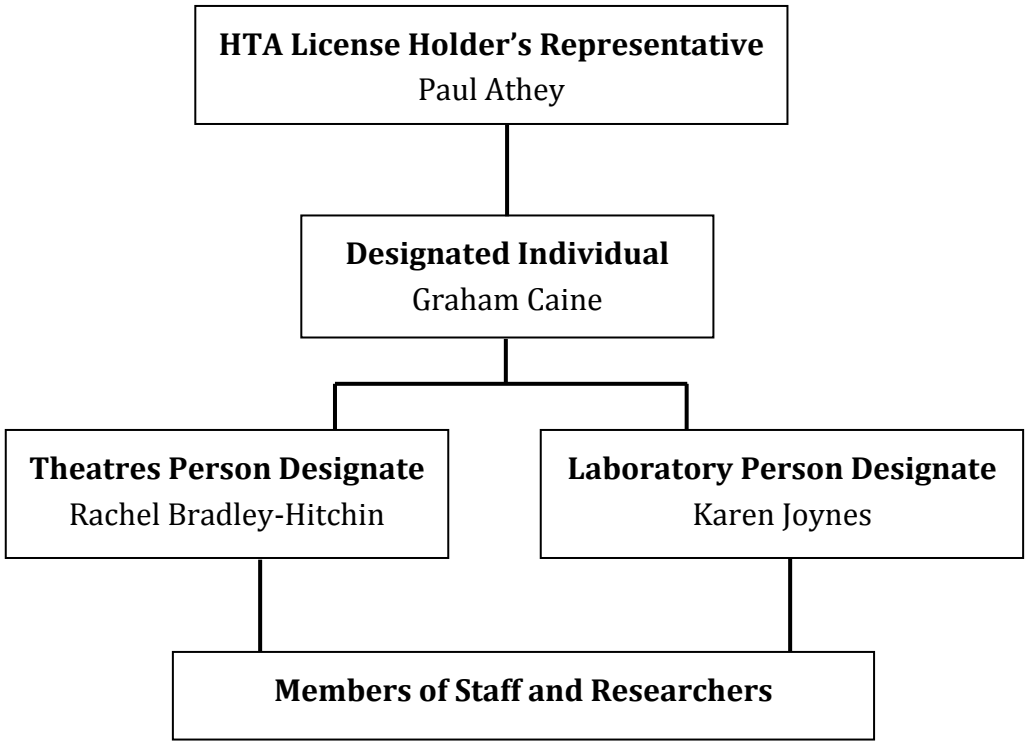
It is also important that the research community and the public have confidence that all human samples for research are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly. The trust requires that all human samples should be treated similarly and that research using any human material should meet the same standards of quality management as set out in this Quality Manual.

The key quality objectives are to establish an effective QMS that will:

- continue to evolve to demonstrate an enduring commitment to quality improvement
- provide a robust but practical framework for compliance with the licensing obligations of the HT Act and to the standards required by the HTA
- be an integral component of the Trust's research governance framework

- have the confidence of and be fully embedded into practice by all staff carrying out research
- engender the highest levels of trust and confidence in our stakeholders and the broader public
- enhance the Trust's reputation for the delivery of research of the highest quality and ethical standards

17.10. Management Structure



17.11. Responsibilities

A. Licence Holder

The Licence is held by the Trust and the licence holder's representative is a named individual in a senior managerial role who should be senior to the DI and able to substitute for the DI where necessary.

Although the role of the Licence Holder does not impose duties that are expected of the DI, the Licence Holder has the right to apply to the HTA to vary the licence, which may include recommending a new DI where, for example, the DI is unable to continue their role.

References on the role of the Licence Holder

http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersunderthehumantissueact2004.cfm

B. Designated Individual (DI)

The DI must:

- be in a position within the licensed organisation to ensure that the activities are conducted properly by individuals who are suitable (and appropriately trained) to carry out those activities and that all necessary legislative and regulatory requirements are complied with
- have knowledge and understanding of the HT Act and the relevant HTA's Codes of Practice
- have time to carry out the role of DI in addition to their substantive role
- ensure compliance with licence conditions
- demonstrate managerial capability, ensuring quality and supervisory responsibility to effect change
- have links to senior management/board level
- know when to seek specialist advice to perform his/her role.

In addition, the DI will:

- act as a key point of contact for enquiries to the HTA; be responsible for investigating and reporting adverse event (including to the HTA, as appropriate)
- meet regularly with the Licence Holder or representative to provide briefings and updates as part of the monitoring of the operation and compliance with the licence
- be informed of and authorise, as appropriate, all research and related activities in the Trust using human tissue, in accordance with the Standard Operating Procedures (SOPs).

References For the role of the DI:

http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersunderthehumantissueact2004.cfm

C. Person Designated (PD)

Individuals can be nominated as Persons Designated (PD) by the DI to work under the direction of the licence in support of the DI. PDs do not have the legal duties of the DI as set out in the HT Act (Section 18) but the role of the PD carries with it the ability to "direct" others in relation to the HT Act, e.g. to assist in developing and implementing the SOPs and offering advice and guidance to those working with human samples at a satellite site.

17.12. Compliance

It is important for the continuation of research, the reputation of its researchers and that of the Trust more broadly, that the Trust adheres to its HTA licence and adopts best practice, including robust and effective quality management, to its activities involving human tissue. If any staff or researchers knowingly breach the HT Act, the provisions of the HTA licence, the HTA Directions or Codes of Practice, or the Trust's related policies and Standard Operating Procedures, detailed in the Quality Manual, they may be subject to the Trust's disciplinary procedures

17.13. Standard Operating Procedures (SOPs)

As part of the QMS, the following SOPs have been developed, detailing polices and instructions on all the processes that affect the quality and safety of human samples used in research:

SOPs provide a uniform approach to the performance of specific functions to ensure continuity and consistency across the Trust. They have been produced in line with the relevant HTA's Codes of Practice (see 2.4 above) and should be read in conjunction with them.

Incorporated into each of the SOPs are the requirements for risk assessment, where appropriate, more detailed local procedures, training, audit and monitoring requirements, and sources of advice and further guidance.

17.14. HTA Standards

1. **Consent -** [This standard is fulfilled by procedure - Trust Consent Policy]
2. **Governance and Quality Management Systems -** [This standard is covered by SECTION 9 of the quality Manual]
3. **Facilities and Equipment -** [This standard is covered SECTION 11 of the Quality Manual]
4. **Disposal -** The disposal of tissue and other waste is described in [Waste Disposal Policy and Procedure and SOP TR 35]