Request

As no information is provided on the Churchill or JR website or Radiotherapy pamphlets, under the FOI act I would be grateful if you could advise what the Churchill QA/QC procedures for inspection and testing of the Linear Accelerators are and whether such inspection and testing is undertaken weekly or monthly and who is responsible for the programme and auditing thereof.

By quality assurance in Radiotherapy I mean the organizational structure, responsibilities, procedures, processes and resources required for implementing QC management and formally accredited to say ISO9000 all those procedures that ensure consistency of the medical prescription and the safe fulfilment of that prescription as regards dose to the target volume, together with minimal dose to normal tissue and adequate patient monitoring aimed at determining the end result of treatment.

I would assume the Churchill Hospital Radiotherapy department has a written QC programme and operates an appropriate QC verification system and that it is routinely used to ensure accuracy and correct alignment in terms of beam constancy, imaging and in-vivo dosimetry. I would also like to know how much time is devoted to QC per week or per month and if monthly (based upon reliance on constancy testing) is any Risk Assessment undertaken to determine the QC content and maintenance/testing schedules plus risk to patients if the QC is not strictly adhered to and regularly audited.

The reason I raise this FOI request is because there is no information in your Hospitals online information or published information or Radiotherapy department literature which is strange in this day and age when nearly all organizations whether private or governmental have to or should or are in fact pleased to publish such information as a key performance indicator.

Response to FOI Request Ref 6653

The organisational structure of the Radiotherapy Physics (RTP) Department is laid out in Appendix 1.

Overall responsibility for accuracy of dose delivery (traceable to the national primary standard at the National Physical Laboratory, Twickenham) and the QA programme lies with the Head of Radiotherapy Physics. This is devolved to the relevant Principle Physicists (8B) via the Radiotherapy Physics Operational Manager.

All activity relating to the above is under the framework of:

Legislation
The Ionising Radiations Regulations 1999 (HSE Statutory Instrument 1999 No. 3232; ISBN 0 11 085614 7) and associated documentation notably;
HSE Guidance Note PM77 Fitness of equipment used for medical exposure to ionising radiation (PM77 Issue 3 revised 2013)
The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (HSE Statutory Instrument 2000 No. 1059; ISBN 0 11 099131 1) amended 2006, 2011.

Codes of Practice
Code of Practice for High-Energy Photon Therapy Dosimetry based on the NPL Absorbed Dose Calibration Service. Physics in Medicine and Biology. 1990 Vol 35 (10): 1355-1360.
The IPEM code of practice for electron dosimetry for radiotherapy beams of initial energy from 4 to 25 MeV based on an absorbed dose to water calibration. Physics in Medicine and Biology. 2003 Sep 21;48(18):2929-70.

National Guidelines
Institute of Physics and Engineering in Medicine best practice reports, in particular:
Report 81: Physics Aspects of Quality Control in Radiotherapy
Report 94: Acceptance Testing and Commissioning of Linear Accelerators
Report 96: Guidance for Clinical Implementation of Intensity Modulated Radiotherapy

The Radiotherapy Department achieved BS EN ISO 9001:2000 accreditation in August 1998 via Lloyd's Register LRQA (Certificate No: LRQ 0960167) and the Radiotherapy Physics Service (on the same certificate) in September 2004. This has been maintained since and in July 2016 transitioned to ISO 9001:2015 Certificate Identity Number 10004579.

Quality control testing assessment is carried out in the department on a daily, weekly, monthly, quarterly and annual basis and all patient treatment plans are assessed before and during treatment.

Daily QC (1 hour per machine prior to treatment):

All clinical energies (photon and electron) used for treatment are checked for stability and the output (calibration) of each is checked with a calibrated relative device. Positioning of

beam collimation and machine features used for individual patient set-up are checked. Patient position verification imaging systems checked. All safety interlocks and systems checked.

Weekly (1 hour)
Output calibration (absolute dose measured with field instrument traceable to NPL) and dosimetry of beam modifiers checked. Further functionality tests of dynamic beam collimation devices.

Monthly (2 days – Saturday & Sunday)
All of the above in greater detail and with different equipment. Checking further aspects of the beam characteristics. Imaging QC. Mechanical checks on isocentre position. Test plan check of planning system.

Quarterly (Incorporated into monthly QC up to 0.5 day extra)
Period schedule ensuring all aspects of machine (different field sizes, gantry angles etc.)

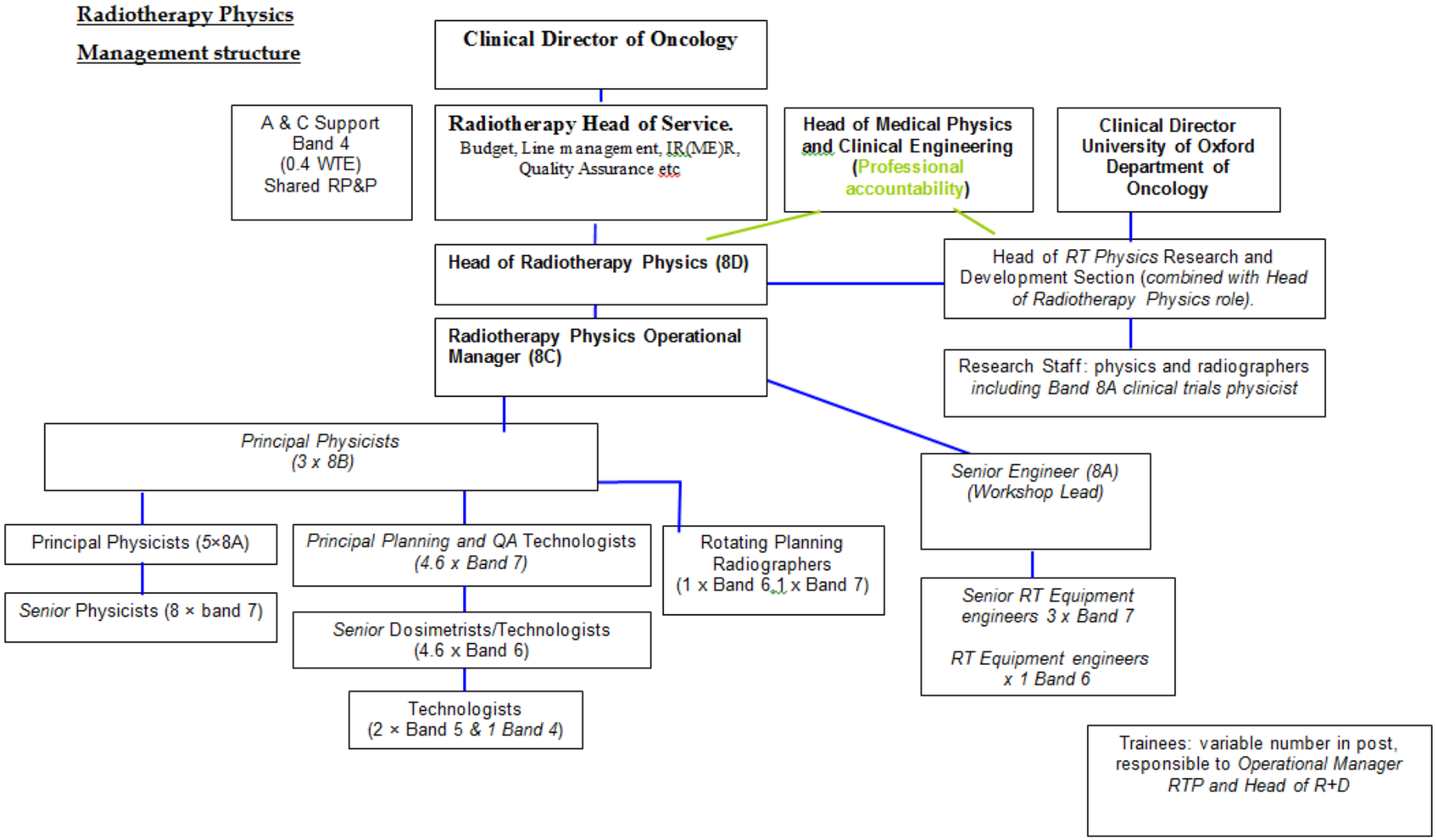
Annual (5 x 12 hour days – machine out of clinical use for 1 week)
Check of beam dosimetry under commissioning conditions.

Patient
All plan parameters and prescription checked against relevant clinical protocol. Independent dosimetry check of dose prescribed and delivered.

Quality System
There is an annual periodic audit process which follows the patient pathway and audits are reviewed through the Radiotherapy Governance group which meets monthly. There are further audits to comply with legislation (IRR 1999 and IR(ME)R 2000) which are also reviewed through the Governance group.

All QC is managed via our accredited QM system. All performance indicators have to lie within strict tolerances and if they fall outside these tolerances it is proscribed in our QM system what action is to be taken.

Appendix 1


Radiotherapy Physics
Management structure
Clinical Director of Oncology
A & C Support
Band 4
(0.4 WTE)
Shared RP&P
Radiotherapy Head of Service.
Budget, Line management, IR(ME)R, Quality Assurance etc
Head of Medical Physics and Clinical Engineering (Professional accountability)
Clinical Director University of Oxford Department of Oncology
Head of Radiotherapy Physics (8D)
Head of RT Physics Research and Development Section (combined with Head of Radiotherapy Physics role).
Radiotherapy Physics Operational Manager (8C)
Research Staff: physics and radiographers including Band 8A clinical trials physicist
Principal Physicists
(3 x 8B)
Senior Engineer (8A)
(Workshop Lead)
Principal Physicists (5×8A)
Principal Planning and QA Technologists
(4.6 x Band 7)
Rotating Planning Radiographers
(1 x Band 6 1 x Band 7)
Senior Physicists (8 × band 7)
Senior Dosimetrists/Technologists
(4.6 x Band 6)
Senior RT Equipment engineers 3 x Band 7
RT Equipment engineers x 1 Band 6
Technologists
(2 × Band 5 & 1 Band 4)
Trainees: variable number in post, responsible to Operational Manager RTP and Head of R+D

OXFORD UNIVERSITY HOSPITALS NHS *FOUNDATION* TRUST

RADIOTHERAPY DEPARTMENT QUALITY MANUAL

Radiotherapy Head of Service

Table of Contents

Record of *Minor Changes and/ or* Manual Amendments

Date	Section/ Page	Details of Change
04/07/2016	8.3 pages26 & 27	Amended to more clearly show that design & development applies across the department, not specifically to treatment plans.
	9.3 page 32	Amended to more accurately reflect Management Review agenda.

0 INTRODUCTION

0.1 General

The exposure of patients to ionising radiations is subject to national legislation and compliance with various regulatory agencies. The hazardous nature of radiation associated with the delivery of radiotherapy services is of special concern. The adoption of a quality management system was a strategic decision for the Oxford University Hospitals NHS Foundation Trust (OUH), recognizing that a robust quality management system would help our overall performance and form an integral component for development initiatives.

A fundamental objective is to provide curative and palliative radiation treatment and associated care to patients within a compassionate environment.

A further objective is the care and support of our establishment and its potential impact on the environment and individuals due to use of ionising radiations.

0.2 Quality Management principles

In *order to deliver* excellent service provision and to ensure that all operational activities function to the same level of efficiency, *the Radiotherapy Department* operates a quality management system for all patients currently under the care of a Clinical Oncologist, to the Standard BS EN ISO 9001:2008, verified by a recognised Certification Body (Lloyds Register Quality Assurance Ltd). This provides both quality assurances for *the* patient, *purchasers and suppliers,* and effective quality management for *the department. The Radiotherapy Department intends to achieve transition to BS EN ISO 9001:2015 by September 2018.*

For the purposes of this manual, *the Radiotherapy Department* is defined as all patient services for patients currently under the care of a Clinical Oncologist.

This document contains the statement of Quality Policy for *the department* to declare *the department's* commitment to achieving consistent quality standards. It also defines the quality approach in all key managerial functions, responding to each element of the International Standard for Quality Systems, BS EN ISO 9001: *2015. By defining* the management organisation for quality, *describing* the system structure and cross-referring to individual operational procedures and forms that affect quality *it provides a route map of the Department's Quality System.*

Non-Oncology employees may read this document; in this case we draw the reader's attention to the statement regarding reproduction or disclosure of documents on the title page of the manual.

0.3 Process approach

0.3.1 General

In order to achieve consistent and predictable results effectively and efficiently we adopt a coherent system whereby activities are understood and managed as interrelated processes. Our intent is to improve patient and staff ("customer") satisfaction by meeting their requirements. Adopting a process approach ensures:

- *understanding and consistently meeting requirements;*
- *considering processes in terms of added value;*
- *achieving effective process performance;*
- *improving our processes and services by evaluating data and information.*

Figure 1 illustrates the process linkages as reflected within this Manual. Customers play a significant role in defining the requirements needed by the Radiotherapy Department to meet all stages of our quality management system.

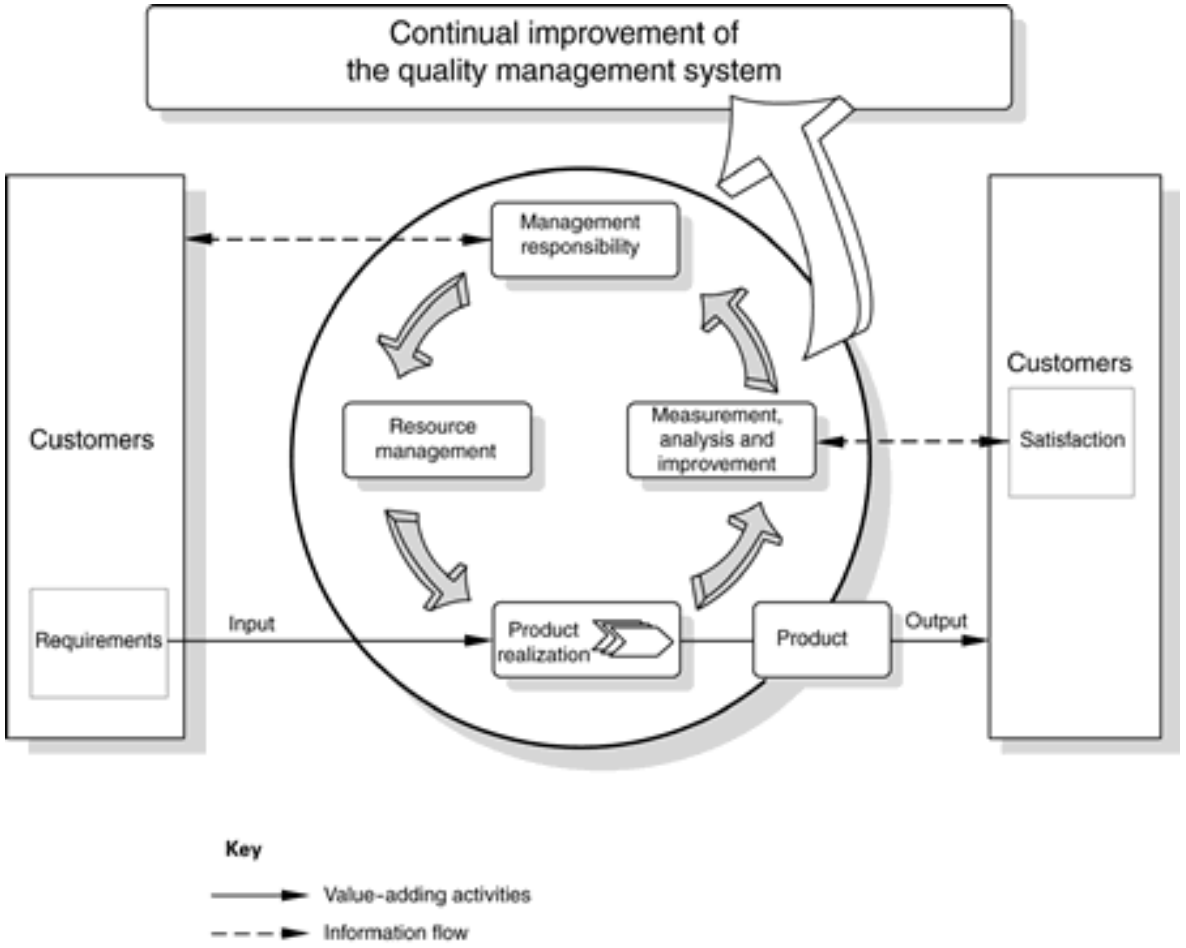
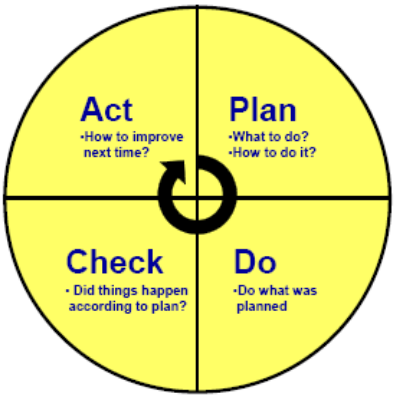


Figure 1. Quality System Processes.

0.3.2 Plan-Do-Check-Act cycle

The methodology known as "Plan-Do-Check-Act" (PDCA) is applied to all processes and to our quality management system as a whole.



"Plan"	*Establish the objectives and processes necessary to deliver results in accordance with customer, statutory and regulatory requirements and the organisation's policies; extent of planning depends on risk*
"Do"	*Implement the processes;*
"Check"	*Monitor and measure processes and product against policies, objectives and requirements for the product and report the results;*
"Act"	*Take actions to continually improve process performance;"*

Figure 2. Schematic representation of a single process within the system.

0.3.3 Risk-based thinking

Risk is the effect of uncertainty on an expected result and the concept of risk-based thinking has always been implied in ISO 9001. Risk-based thinking therefore means considering risk qualitatively and quantitatively when defining the rigour and degree of formality needed to plan and implement actions to address risks and opportunities within the quality management system, as well as its component processes and activities. We adopt the OUH approach using the risk matrix depicted in Figure 3 and following the OUH Risk Management Strategy.

	Likelihood				
Consequence	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

In grading risk, the scores obtained from the risk matrix are assigned grades as follows:

1 - 3	Low risk
4 - 6	Moderate risk
8 - 12	High risk
15 - 25	Extreme risk

Figure 3. OUH Risk matrix

Radiotherapy Department Profile

The Radiotherapy Department is part of the Oxford University Hospitals NHS *Foundation* Trust (OUH, *or the* Trust).
The unit provides a Radiotherapy, *Brachytherapy and Therapeutic Radioisotope* service to patients in Oxfordshire, Buckinghamshire, parts of Wiltshire and *Milton Keynes, in addition to* other areas as referred.

The *Radiotherapy* department is part of the *Surgery and* Oncology D*ivision*. The Oncology department encompasses both Clinical and Medical Oncology and the Radiotherapy service includes Radiotherapy Physics. There are professional lines of accountability from Radiotherapy Physics to the Department of Medical Physics and *Clinical* Engineering which is also part of the *Oncology and Haematology Directorate within the Surgery and* Oncology *Division*.

There are strong links with the University Department of Oncology, with many joint appointments within the medical, physics and radiographer staff.

To *deliver an* excellent service and to ensure that all operational activities function to the same level of efficiency, for all patients currently under the care of a Clinical Oncologist, *the Radiotherapy Department* operates a quality management system to the Standard BS EN ISO 9001:2008, verified by a recognised Certification Body. This provides both quality assurance for patients and effective quality management for *the department. This quality manual covers the requirements of the revised standard (ISO 9001:2015) in anticipation of achieving transition to the new standard in July 2016.*

For the purposes of this manual, *the Radiotherapy Department* is defined as all patient services for patients currently under the care of a Clinical Oncologist. The current quality management system does not cover ward nursing practice, chemotherapy or the Medical Oncology practice, although in due course it is anticipated that the quality management system *may* cover the entire Oncology department to the standard BS EN ISO 9001

1 SCOPE

The *Radiotherapy Department* needs to *demonstrate its ability to provide consistent high quality therapeutic services that meet our customers (patients and staff) needs. In addition, statutory and regulatory requirements demand that a quality system is in use.*
We also aim to enhance customer satisfaction through effective application of the quality system, including processes for its continual improvement.

The *above services are limited to* prescription and delivery of treatment for patients currently under the care of a Clinical Oncologist working within the department of Oncology (either as a substantive NHS consultant or University/ *NHS Consultant post* with Honorary Consultant status *or consultant employed jointly with another Trust holding an honorary contract with OUH*), including external beam Radiotherapy, brachytherapy treatment, and therapeutic isotope treatment up to the end of treatment and discharge including associated patient administration and support services.
This involves the work of Clinicians, Radiographers, Scientists, Technologists, Nurses, Assistant Practitioners, Radiotherapy Helpers and Administrative staff, and other specialist suppliers to Oncology.

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of our Quality System. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. Other references are detailed in specific procedures as appropriate.

ISO 9001:2015, Quality Management System Requirements

Ionising Radiations Regulations 1999. SI 1999/3232. London: HMSO.

The Ionising Radiation (Medical Exposure) Regulations 2000, SI 2000/1059. London: HMSO.

The Environmental Permitting (England and Wales) Regulations 2010, SI 2010/675. London: HMSO.

The Medicines (Administration of Radioactive Substances) Regulations 1978, SI 1978/1006. London: HMSO.

The Medicines (Radioactive Substances) Order 1978, SI 1978/1004. London: HMSO

Department of Health. Bleehen Report. Quality Assurance in Radiotherapy: A quality management system for radiotherapy PL/CMO (94).7. London: DH, 1994.

Donaldson S. R. (2007). Towards Safer Radiotherapy. London: British Institute of Radiology, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, Society and College of Radiographers, The Royal College of Radiologists.

Additional documents and legislation are listed in procedures where they have specific relevance.

3 TERMS AND DEFINITIONS

The terms and definitions detailed in ISO 9001:2015 have the same relevance and meaning within our quality system. Due to the legislation governing our work with ionising radiations there are specific terms that warrant including herein.

3.1 External beam ionising radiations

Under the Ionising Radiations Regulations (1999) and the Ionising Radiations (Medical Exposure) Regulations 2000 (IR(ME)R) the responsibilities of duty holders are defined as follows:

The employer
Is responsible for providing a framework for radiation protection of patients. This is the Chief Executive of the OUH.

The Radiation Protection Advisor
Must be available for consultation by the employer. Their duties are to advise the employer on the safe use of ionising radiations.

Radiation Protection Supervisors
Are employed in supervisory positions within each area where ionising radiations are used both for diagnostic and therapeutic purposes. Their duties encompass both monitoring and supervising the safe use of such radiations.

The referrer
Referrer must be "… a registered medical practitioner, dental practitioner or other health professional who is entitled … to refer individuals for medical exposure to a practitioner …" (Page 21. 2.15 – 2.17).

The *IR(ME)R* practitioner
Defined as "a registered medical practitioner, dental practitioner or other health care professional who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure". (Page 22. 2.18 – 2.25)

The operator
Defined as "any responsible person who carries out the practical aspect of the medical exposure". (Page 24. 2.30 – 2.40)

The Medical Physics Expert
Defined as "a state registered clinical scientist with corporate membership of the IPEM (MIPEM) or equivalent, and 6 years of appropriate experience in the clinical speciality". (Page 25. 2.41 – 2.44)

All references quoted are with respect to the Medical and Dental Guidance Notes, IPEM 2002.

3.2 Radioactive materials

Permits

Under the Environmental Permitting Regulations 2010 (EPR2010) permits are issued by the Environment Agency authorising us to store, use and dispose of radioactive materials.

Radioactive Waste Advisor

Must be appointed to control the disposal of radioactive waste from the OUH premises.

ARSAC

The Administration of Radioactive Substances Advisory Committee (ARSAC) operating under the Medicines (Administration of Radioactive Substances) Regulations (MARS1978, amended 1995) states that only appropriately trained and certified medical practitioners may administer radioactive material for the diagnostic or therapeutic exposure of patients.

Current entitled duty holders undertaking the above roles and duties are listed in the IR(ME)R manuals and kept by their departmental professional leads.

4 CONTEXT OF THE ORGANISATION

4.1 Understanding the organisation and its context

Figure 4. The OUH key values that help us deliver our purpose

The Hospital organisation (in Appendix 1 and 2) details the management structure within the OUH Foundation Trust and the supporting services available.

Radiotherapy and RT Physics Meeting Structure

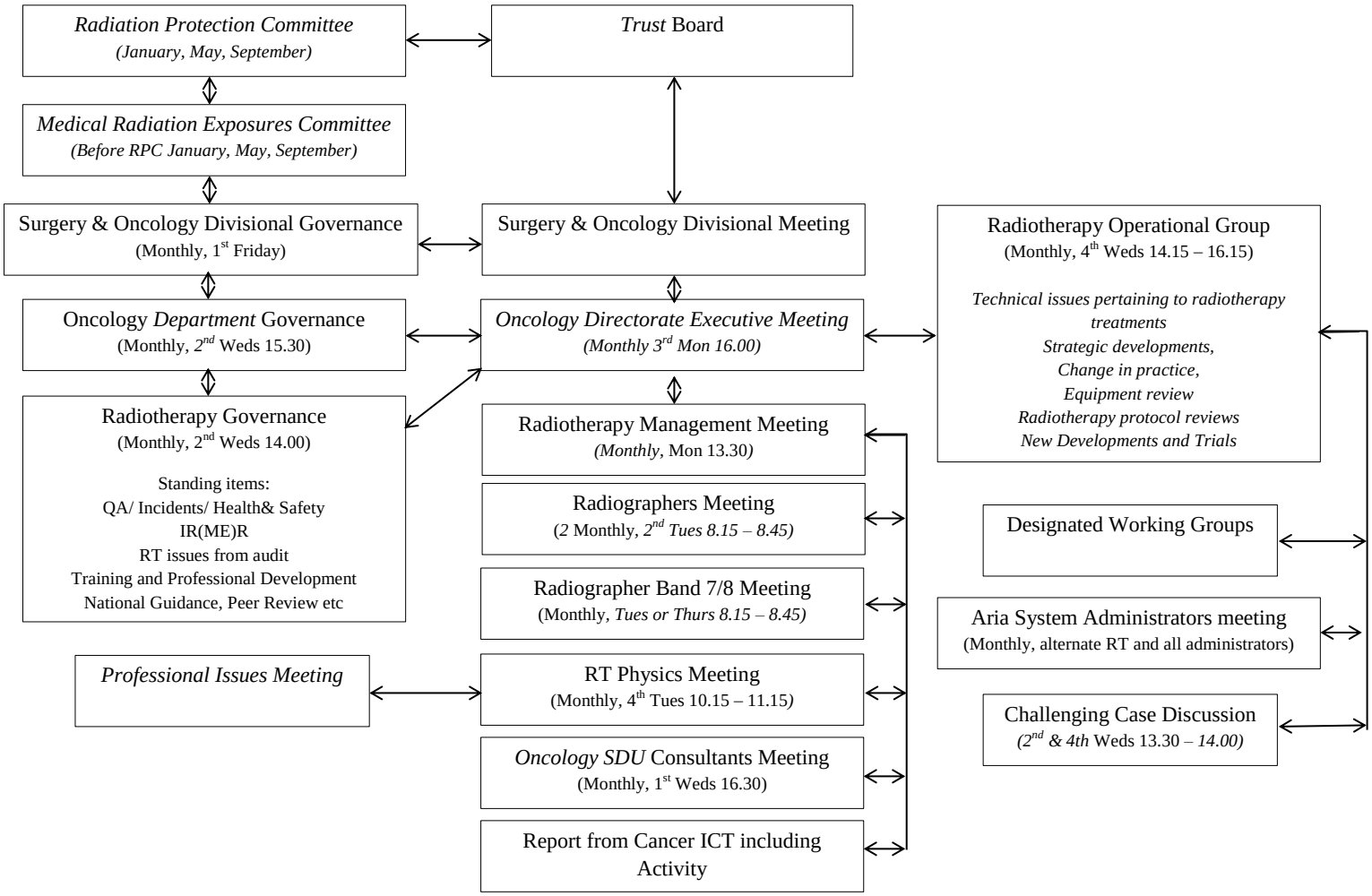


Figure 5. M*eeting Structure and flow of information*

The OUH is governed by a Board of Directors. The Board has overall responsibility for the activity, integrity and strategy of the Trust and is accountable, through its Chairman, to the Strategic Health Authority and the Secretary of State for Health.
The Trust Management Executive is the senior managerial decision-making body for the Trust. It is chaired by the Chief Executive and consists of the Trust's Executive Directors, the six Divisional Directors, as well as representatives from Oxford University.
The Executive has the following Committees:
Clinical Governance
Workforce
Education
Health Informative
Performance
Review
Strategic Planning
Research and Development

The Oncology and Haematology Directorate meeting is chaired by the Clinical Director and attended by senior managers across the directorate responsible for the strategic planning and operational delivery of services provided in the Oncology and Haematology Directorate. The group report to the Division any matters requiring further discussion/approval.

The relationships between the meetings held within Radiotherapy and Radiotherapy Physics are shown in figure 5.
The Department has established, documented, and implemented a quality management system which is subject to continual improvement in accordance with the requirements of ISO 9001:2015.

Process Flow Charts in the appendices describe the main processes in use throughout the department and its interactions with other departments in the Hospital. These processes are managed in accordance with the requirements of ISO 9001:2015.

Appendix 5 describes the interactions with processes that are outsourced to supporting services, whilst sections 4.2.2 and 4.2.3 detail relevant companies and organisations external to the Hospital.

*External and internal issues are monitored and reviewed annually at management level (**OCC-QS-L2-001**, Management review).*

4.2 Understanding the needs and expectations of interested parties

Our services are solely healthcare related and as such geared to the wellbeing of our patients. Other interested parties are those who have an impact or potential impact on our ability to provide products and services to meet both customer and regulatory requirements. These include as examples: Patients, Clinicians, Medical Physics, Radiographers, OUH trust staff, Peripheral Hospital staff, Commissioners, Health Education England, Legislatory bodies e.g. CQC, HSE, and NHS England. The requirements of these interested parties are evaluated and level of engagement determined by interest, involvement, influence, attitude and impact.

4.2.1 Other hospital services and departments

Patient surveys are regularly conducted both by the wider OUH and within our Quality System. These are reviewed quarterly and actions taken to improve and adapt to our customer's needs.

Appendix 5 illustrates the services within our organisation but outside of the scope of our quality management system that impact on our services. Service provision is monitored by review at operation level by the Directorate Managers and application of incident reporting (via Datix), including service currently supplied by Genesis in Milton Keynes. Clinical governance is proactive and constantly reviews service deficiencies and the actions taken to correct and improve services. These aspects are a requirement for our Organisation's continued compliance with the Care Quality Commission regulations (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).

4.2.2 Regulatory authorities

Other interested parties are those who regulate and monitor our use of ionising radiations. These aspects are documented within our Radiation Protection policies and procedures. The following competent authorities are most relevant:

- *Department of Health (DoH)*
- *Care Quality Commission (CQC)*
- *Environment Agency (EA)*
- *Counter Terrorism Security Advice Centre (CTSA)*
- *Health and Safety Executive (HSE)*
- *Medicines and Healthcare products Regulatory Agency (MHRA)*

We have regular inspection visits from the CQC, EA and CTSA and are required to provide evidence of compliance with their requirements. The former two are reported to as and when a radiation related incident occurs. Completion of externally reported incidence requires our complying with their responses and demonstrating robustness in our actions and procedures. Ongoing compliance is monitored by direct liaison between the Head of Machines (as the Radiation lead) and the competent authorities, supported by quarterly attendance at Radiation Protection Committee Meetings. A report is provided by the Head of Machines to this meeting, who are authorised to monitor radiation matters within the organisation.

4.2.3 Equipment service providers

Our services are heavily dependent on the efficient, safe use of medical equipment and devices. The equipment listed below forms part of the Managed Equipment Service with a 'First Line Support' contract. These include:

1. *Linear accelerators - Varian Medical*
2. *Aria (Rad Onc) - Varian Medical*
3. *Somavision - CMS*
4. *Respiratory gating system – Varian Medical*
5. *Acuity Simulator – Varian Medical*
6. *GE CT scanner - GE*
7. *ExacTrac System - BrainLab*

Compliance with contracts is monitored on a quarterly basis and regular meetings held with the suppliers. Records of all maintenance and service are logged within the relevant sections and inspected. Robust handover procedures exist and all patient related equipment is checked in accordance with nationally accepted processes and best practice.

4.2.4 Support service providers

We have management provision to support our services effectively and efficiently. These include:

- *Lloyds Register Quality Assurance (ISO 9001certification body)*
- *CQC*
- *Public Health England*

LRQA complete regular inspections where our systems are independently monitored for compliance with standards and best practice.

4.2.5 Software support

Major software critical to the safe and efficient running of our managed equipment service (as detailed in 4.2.3) are monitored and controlled within the Department.

Other software supporting our service provision are managed by departments external to our quality system, e.g. OUH IM&T cover all Trust PCs and software installed, or externally to the Trust e.g. Gael Software for Q-Pulse.

4.3 Determining the scope of the quality management system

The Quality System described in this Manual and the corresponding Quality Assurance Procedures cover the following services:

The prescription and delivery of treatment for patients currently under the care of a Clinical Oncologist working within the department of Oncology (either as a substantive NHS consultant or University/ *external NHHS* post with Honorary Consultant status), including external beam Radiotherapy, Brachytherapy treatment, and Therapeutic Isotope treatment up to the end of treatment and discharge including associated patient administration and support services.

An organisation chart depicting those staff groups covered by this Quality System and the managerial accountability is depicted in Appendix 3. All the services embraced within this Quality System comply with the statutory and regulatory requirements of competent authorities and Professional Bodies.

We will ensure the health, safety, and welfare of our staff, patients, visitors, contractors, and others who may be affected by the operations of the department. To this end, all work is carried out in accordance with OUH Policies. The generic services covered are illustrated in Figure 6 below.

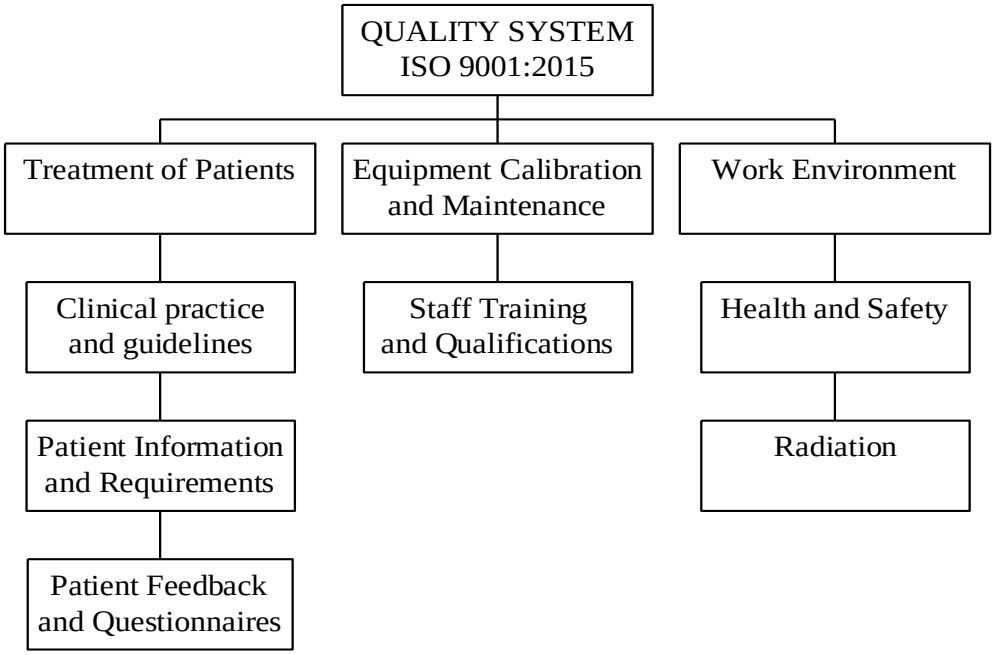


Figure 6. Generic processes within the boundaries of the Quality System

The needs of our customers are paramount and embraced within our culture.

4.4 Quality management system and its processes

The Radiotherapy Department has established, documented, and implemented a quality management system which is subject to continual improvement in accordance with the requirements of ISO 9001:2015.

Process Flow Charts in the appendices describe the main processes in use throughout the Departments and their interactions with other departments in the Hospital. These processes are managed in accordance with the requirements of ISO 9001:2015

Section 4.2 describes the interactions with processes that are outsourced to supporting services/and companies external to the Hospital.

Documents supporting the department are distributed within Q-Pulse or in hard copy as appropriate. A record is maintained for all copies of an individual document within the distribution record in Q-Pulse. The process is detailed within ***OCC-QS-L2-003*** *Document and Data Control*

5 LEADERSHIP

5.1 Leadership and commitment

5.1.1 Leadership and commitment for the quality management system

The Department has established a quality management system that is designed to comply with the requirements of the ISO 9001:2015 standard. The Head of Radiotherapy (Clinical Unit Operations Manager under OUH IR(ME)R documentation) has overall responsibility for the services of Radiotherapy, Radiotherapy Physics, and Therapeutic Radioisotopes and reports via the Director of Surgery & Oncology to the OUH Chief Executive, and they and the entire Department's staff are committed to maintaining service excellence. See Appendix 3

Senior management attend the Radiotherapy Governance meetings where clinical governance and patient questionnaire responses are reviewed. Information is also passed to the Matron for the Oncology and Haematology Directorate for inclusion in the monthly report.

Compliance with the authorities regulating the use of radiation and radioactive material demands a management structure and involvement that accords with the requirements of the ISO 9001:2015 standard.

This is given effect through our Radiation Protection Committee and supported by the procedures detailed within the Radiation Protection aspects of our Quality System.

The Quality Management Representatives (from radiotherapy physics and radiographers) attend separate monthly staff meetings to give and receive feedback regarding the quality procedures.

Clinical Oncology and Medical Oncology Consultants meet monthly, *the consultants are divided into 8 tumour site groups each with a clinical lead, and an Oncology Service Delivery Unit (SDU) clinical leads meeting takes place monthly, with representative attendance at the Directorate meeting.*

There is a monthly meeting of the Radiotherapy Operational Group, at which any proposed changes to technique / procedure may be discussed and regular *clinical* protocol review take place. *Any operational issues are also raised here.*

A monthly Radiotherapy Service Clinical Governance meeting is attended by the RSM, Head of Radiotherapy Service, Head of Radiotherapy Physics, *Head of Therapeutic Isotopes* and Radiation Protection Advisor to discuss ongoing matters within *Oncology*. The elements of Management Review are discussed primarily within this forum, reviewing current performance and improvement opportunities. The meeting is chaired by the Oncology Governance Lead Clinician (if they are a clinical oncologist) or nominated Radiotherapy Governance Lead. *There are close links with the Oncology & Haematology Governance, Divisional Governance, Therapeutic Nuclear Medicine Group, and Radiation Protection Committee meetings to ensure information is shared appropriately.*

Multi-disciplinary meetings are held *monthly* in the Cancer Centre meeting rooms on *the first Wednesday afternoon of the month. Mortality and morbidity or audit meetings take place followed by an academic presentation.*

Directorate and Divisional meetings are held monthly. Additional meetings are held within the Trust at Directorate level and above, with information cascaded to relevant Managers where necessary.

5.1.2 Customer focus

The current and future needs and expectations of patients and the requirements for achieving customer confidence are agreed in contracts with NHS commissioners.

The Departments establish the needs and expectations of their patients/customers by liaison with purchasers and other healthcare providers. During major service change within the department, patient representation and views are actively sought through meetings with all stakeholders.

The Departments will be responsive to the needs of patients and their carers at all times. Patient Satisfaction Surveys are regularly completed and analysed to assess levels of patient satisfaction and address any deficiencies that arise. GP Datix forms are reviewed and actions are circulated within the monthly Quality Report written by the Oncology & Haematology Directorate Matron.

The processes for meeting patient/customer requirements are communicated to all staff in the Departments and are continually evaluated for improvement. Regular staff meetings are held for staff groups across the Department to discuss patient and other issues.

The Department has established service agreements with companies and suppliers external to the OUH for the provision of specialist services. Compliance with the service agreements is monitored with Datix forms being raised when necessary, which are reported and investigated as appropriate and escalated through the Trust.

5.2 Quality policy

The OUH has an ethos of 'Delivering Compassionate Excellence', with the Trust core values of Excellence, Compassion, Respect, Learning, Delivery and Improvement

As taken from the OUH Delivering compassionate excellence Trust Values intranet site;
"The aim of having a new set of values is to use them to steer our behaviours in our working life and, importantly, help us explain to our patients, staff and stakeholders what is important to us as an organisation. The …. core values (above) were drawn up from the themes identified by staff."

The department is committed to incorporating the Trust values into the department, aiming to:

- *Achieve the highest technical standards of patient care and meeting or exceeding patient and family expectations regarding comfort and compassion,*
- Meeting all legal and statutory requirements *and conform to best practice*
- *Develop* continual improvement, achieving consistently high quality standards and taking a quality approach to all key managerial functions.

During a course of treatment we *will*:

- Provide patients with the highest standards of care *delivered with the highest class of professionalism*
- Respect patient's dignity, individuality and personal preferences.
- Develop a partnership in which patients wishes are respected.
- Involve and support patients in decisions regarding their treatment.

We *will* also provide *a workplace* where:

- Staff feel valued.
- Staff can achieve personal and professional growth.

We welcome comments and suggestions *which we use* to help improve our service.

The Department is committed to establishing and reviewing the quality objectives of the Quality System and communicating these to all members of the department in group meetings.

This policy will be fulfilled through the adoption and implementation at all times of the Quality Management Systems and Procedures required by BS EN ISO 9001

This Quality Manual *and associated* Quality Assurance Procedures constitute the Quality *Manual* of *the Radiotherapy Department*. It will be reviewed to ensure it continues to *support the strategic direction of the department and provides a* suitable *framework for setting* the Quality Objectives of the *Radiotherapy Department and for supporting the Trust in its desire to deliver compassionate excellence.*

T*he Quality Policy is a controlled document and must not be photocopied unless authorised.*

A signed copy of the Quality Policy, demonstrating management commitment can be found on the notice board in the Radiotherapy Reception area.

The Trust values can be expressed as:

"We aim to provide excellent care with compassion and respect"

We will do this by:

- *Taking pride in the quality of care we provide*
- *Putting patients at the heart of what we do and recognising different needs*

- *Encouraging a spirit of support, respect and teamwork*
- *Ensuring that we act with integrity*
- *Going the extra mile and following through on our commitments*
- *Establishing systems and processes that are sustainable*

"We aim to deliver, learn and continuously improve"

We will do this by:

- *Delivering high standards of healthcare based on national and international comparisons*
- *Delivering the best clinical teaching and research*
- *Adopting the best clinical research in patient care*
- *Striving to improve on what we do through change and innovation*
- *Monitoring and assessing our performance*
- *Learning from success and setbacks*
- *Working in partnership across the Health and Social Care Community*

5.3 Organisational roles, responsibilities and authorities

The duties, responsibilities and authority of personnel within *the Radiotherapy Department* who manage and perform activities affecting the quality of services provided to users are detailed below.

The **Clinical Director of Oncology and Haematology** has overall responsibility for strategic *planning* and day-to-day operation of Oncology. Overall responsibility for the professional aspects of the radiotherapy service is delegated to the Head of Radiotherapy Service (this post may be held by the Clinical Director of Oncology and Haematology).
The Radiotherapy Head of Service is responsible for ensuring that adequate resources and trained personnel are available within Oncology to implement the Quality Policy and also takes the lead for Clinical Governance (CG) within the radiotherapy service. The Clinical *Governance* Lead for Oncology has overall responsibility for Clinical governance within Oncology, reporting to the Clinical Director for Oncology and Haematology.

The **Clinical Oncologists** are responsible for decisions regarding treatment for each individual patient's requirements. They are practitioners under the IR(ME)R 2000 regulations. They partake in the clinical training of Specialist Registrars and other staff groups.

The **Radiotherapy Service Manager (RSM)** and **Radiographic Staff** are responsible for the safe and accurate planning and delivery of radiation treatment according to their scope of practice and entitlement under IR(ME)R 2000 to patients and the care of patients undergoing radiation treatment. Staff are operators under the IR(ME)R 2000 regulations *with some staff entitled to work as a practitioner as defined within their job description.*

The **Radiotherapy Technical Services** team are responsible for the maintenance of the equipment used for delivery of radiation treatment. They are operators under the IR(ME)R 2000 regulations.

The **Head of Radiotherapy Physics** *is* responsible for the radiotherapy physics services provided to Oncology.

The **Radiotherapy Physics** team are responsible for the planning of radiation treatment, including brachytherapy, for individual patients and for the ongoing design and development of the radiotherapy treatment service. They are also responsible for the calibration and Quality Assurance of treatment equipment, ensuring that such equipment is fit for clinical use. They are operators and / or Medical Physics Experts under the IR(ME)R 2000 regulations.

The **Administration (Secretarial and Clerical**) **Staff** are responsible for the administration of all Oncology clinics and patient related documentation.

The **Radiotherapy Nurses** are responsible for contributing towards *a holistic approach to* patient care within the Radiotherapy department.

All *Radiotherapy Department* staff have a responsibility for reporting and recording Quality Performance and undertaking tasks in accordance with the documented Quality System Procedures. They will also ensure there is good and effective communication at all levels of the organisation to facilitate the quality objectives of *the department*.

The Radiotherapy Head of Service, Head of RT Physics, and RSM are responsible for establishing Quality objectives within the Department. They are responsible for ensuring that adequate resources and trained personnel are available to implement the policies and for supervising the staff to deliver the services provided.

Job descriptions are reviewed within the OUH Appraisal system, where actions aligned with the Hospitals strategic objectives are agreed.

Only entitled staff are permitted to undertake tasks unsupervised. Details of training are held by the staff member and may also be within Q-Pulse.

*The Quality Team (Appendix 6) is responsible for auditing, recording, and reporting Quality Performance. They report this to the Radiotherapy Clinical Governance meeting. The Management Team monitors patient complaints and other failures to meet agreed norms and ensures corrective action is effective. The Heads of Section/Department approve the issuing of Quality Assurance Procedures (see **OCC-QS-L2-003** Document and Data Control)*

*The performance of the quality management system and opportunities for improvement are regularly reviewed and where appropriate change is implemented (**OCC-QS-L2-012** Change in Practice and Implementing New Techniques).*

An Organisation Chart for the Department is shown in Appendix 3 whilst Appendix 6 identifies the members of the QART Team and their generic responsibilities.

6 PLANNING FOR THE QUALITY MANAGEMENT SYSTEM

6.1 Actions to address risks and opportunities

*Scheduled audits, Department meetings and staff awareness all contribute to reduce or eliminate the potential causes of nonconformity in order to prevent occurrence. Actions may be identified following an Adverse Incident or Near Miss (**OCC-QS-L2-006**, Complaints, Non-conformances and Corrective Action).*

Quality control programmes are put in place to monitor equipment processes and trends assessed to assist in proactively dealing with likely system failures.

Risk assessments for the department are in place and are reviewed within the Radiotherapy clinical governance forum.

Our service developments are supported by a business process that requires all associated risks (financial, reputation, and regulatory) to be assessed. Where risks cannot be avoided they are managed and documented in accordance with sound practice and good governance (OUH Risk management Policy).

6.2 Quality objectives and planning to achieve them

The respective Heads of Departments define quality objectives for services that are consistent with the quality policy, legislative requirements, and the commitment to patient/customer requirements and continual improvement. Department objectives are specific and measurable, and are consistent with the objectives of the OUH. They are discussed and communicated to staff regularly and reviewed within the Radiotherapy Clinical Governance meeting as determined within **OCC-QS-L2-001** (Management Review). *The Radiotherapy Development Plan details the objectives for the Department, review date, outcomes and their alignment with OUH objectives.*

6.3 Planning of changes

The Radiotherapy Department has identified *and established* the activities and resources needed to achieve its Quality Objectives and works to ensure availability of these resources within the constraints of overall OUH Trust resources.

All the routine processes of *the department* are governed by the statutory regulations of the NHS and OUH and by the requirements of the Ionising Radiation Regulations 1999 and the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R 2000).

Therefore the requirements for Quality Management System (QMS) planning can be predicted in advance. These QMS plans are incorporated into the provision of patient care and support services and include resources, quality characteristics, verification activities, criteria for acceptability and records and negotiation of service contracts.

When any new patient care or support service processes and / or improvement of the QMS or service provision are introduced, *New Proposal forms* appropriate to the process requirements *are* prepared *and where appropriate added to the Radiotherapy Development plan*. Likewise, if organisational changes are introduced, *New Proposal forms are* established to ensure that change is conducted in a controlled manner, and that the QMS is maintained during the change (see **OCC-QS-L2-012** *Change in Practice and Implementing New Techniques*).

When the need to change the Quality Management System has been identified we consider the:

- *purpose and consequences of the change;*
- *risks to the integrity of the Quality Management System;*
- *availability of resources*
- *allocation of responsibilities and authorities.*

7 SUPPORT

7.1 Resources

The Radiotherapy Head of Service, Radiotherapy Service Manager, Administrative Manager and Head of Radiotherapy Physics determine *and provide* the resources needed to implement and improve the processes of the quality management system and thereby address and enhance customer/ patient satisfaction. Resources are provided within the budgetary limits set by the Oxford *University* Hospitals NHS *Foundation* Trust.

The commitment to resource management is demonstrated in the following sections.

7.1.1 General

The Management Team regularly reviews the capabilities and constraints on existing internal resources in terms of personnel, equipment and consumables. Similarly, external resources are reviewed and assessed in liaison with the OUH Procurement policies and where risks are highlighted alternative processes and suppliers considered.

7.1.2 People

The Heads of Department in association with the relevant Directorate Managers are responsible for providing suitably qualified and experienced staff necessary for the effective operation of the quality management system. Staff complements are reviewed annually and audited against nationally recommended levels. Only suitably trained staff are authorised to undertake procedures and staff training and competencies are documented. An annual Appraisal is carried out for all staff, where actions aligned with the Hospitals strategic objectives are agreed.

7.1.3 Infrastructure

The Radiotherapy Head of Service reviews (as part of the management review process –see **OCC-QS-L2-001** Management Review) the infrastructure needed to achieve conformity of services within the overall Oncology department. This includes provision and maintenance of:

- Office facilities.
- Equipment, hardware and software.
- Maintenance arrangements.
- Supporting services.

7.1.4 Environment for the operation of processes

Personnel and physical factors of the work environment needed in *the department* to achieve conformity of the provision of care and support services to patients are reviewed as part of procedure **OCC-QS-L2-001** Management Review.
The department aims to fully comply with the Trust Health and Safety arrangements. *Staff participate in routine OUH mandatory training notably Fire safety and Health & Safety training.*

7.1.5 Monitoring and measuring devices

The Radiotherapy Physics department of the Trust undertake the calibration of critical medical equipment.
Radiotherapy equipment is monitored and calibrated by Radiotherapy Physics staff in conjunction with the Radiotherapy Technical Services staff. In addition, Radiotherapy Technical Services staff conduct planned, preventative maintenance services.
Radiotherapy Physics staff are responsible for the operation and care of all radiation monitoring devices.

Where measurement traceability is a statutory or regulatory requirement, measuring instruments and/or equipment are verified or calibrated at specified intervals against measurement standards traceable to international or national measurement standards.

Dose monitoring and control systems are maintained by the Radiotherapy Physics Department to ensure precise delivery and accurate doses of radiation for patient and other exposures (see ***OCC-PDS-L2-003*** *Routine Testing of Machines and Equipment)*

Measuring devices such as ionisation chambers are calibrated and controlled in accordance with National Codes of Practice and to timeframes specified in such codes. Local documentation is written to support the process e.g. ***OCC-PDS-L3-030*** *Definitive Cross Calibration of Ionisation Chambers for X-Ray beams.*

Other medical equipment activities associated with the life cycle of that equipment, from controlled procurement, acceptance, use, storage, management and maintenance through to correct decommissioning and disposal are conducted as per OUH Policies.

7.1.6 Organisational knowledge

The OUH maintains robust communication between senior management and all staff groups to ensure that organisational knowledge is freely available and transparent. Regular 'all staff' meetings are held by the Chief Executive, to which all OUH employees are invited by email. Additional Trust wide information is disseminated by email from the Chief Executive or the head of Internal Communication

All new staff attend an induction programme at which the organisation's ethos, policies and procedures are discussed.

Trust Board videos are added to the intranet for all staff to access when important information is to be circulated. All staff receive an email to inform them that the video has been released

Important Staff updates affecting more than 25% of employees are circulated by internal global email

Staff briefings are posted on the intranet and emailed to staff

Senior Managers' Briefing Sessions (taken from intranet)
These sessions are held every six weeks. The Chief Executive presents important operational information for senior managers and all senior managers (those 8a and above) are expected to attend or send a deputy in their place. The managers are then asked to share the relevant information in their team meeting process to reinforce the important Trust-wide information and issues that need to be addressed

OUH News& You is published bimonthly, and is posted on the OUH internet site and available in printed form from public areas within the Trust, making it available to the public in addition to employees

7.2 Competence

The Department identifies its people resource requirements regularly and updates these requirements during the year in the event of any significant change, and advises senior management of any deficiencies.

The Department has established and maintains procedure **OCC-QS-L2-010** Training to:

- *Ensure all staff are competent to perform the duties and tasks as specified in their job descriptions.*
- *Ensure Training and Personal Development Plans are devised to meet the requirements of the individual's Professional Body and statutory requirements.*
- Determine competency needs for staff performing activities affecting conformity to *process* requirements.
- Provide training to address identified competency needs.
- Evaluate the effectiveness of training at defined intervals.
- Ensure staff are aware of their contribution to the achievement of Quality Objectives.
- Maintain appropriate records of education, training, skills and experience.

Responsibilities that are defined in the quality management system are assigned only to people who are competent on the basis of relevant education, training, skills and experience.
All new staff undergo a formal probationary period to assess their abilities and competencies in carrying out the tasks assigned in accordance with their documented job descriptions.

Training records may be kept in Q-Pulse.

7.3 Awareness

*All new staff are made aware of the way the quality system is used within the department, the Quality Policy and the department's objectives as part of their initial induction programme. All staff are advised, reminded and updated on the quality system, its procedures and changes as part of routine communication within the department. Non- conformances within the quality system are formally discussed at the Radiotherapy Clinical Governance meeting and actions taken where appropriate (see **OCC-QS-L2-006** Complaints, Non-conformance and Corrective Action)*

7.4 Communication

The following framework of regular meetings is maintained within the Department:

- *Heads of Sections (Radiotherapy Head of Service, RSM, Head of Radiotherapy Physics)*
- *Clinicians*
- *Radiotherapy Physics Staff*
- *Radiographer Staff*
- *Therapy isotope Nuclear Medicine & Medical Physics Staff*
- *Focus Work Groups*
- *Machines meeting (RSM, Radiotherapy Physic Operational Manager, Machines and QA Radiotherapy Physicist, Lead Radiotherapy Technical Services)*

These meetings are designed to establish and maintain communication of quality requirements, objectives, and achievements, and the effectiveness of the quality management system. Minutes from these meetings are communicated to all staff where relevant.

In addition, nominated members of staff attend and participate in the Radiotherapy Operational Group and Radiotherapy Clinical Governance meetings where Management Review elements are discussed including current performance and improvement opportunities.

7.5 Documented information

7.5.1 General

The quality management system documentation includes:

- *Statements of quality policy and objectives (in the form of the department development plan).*
- *Procedures, work instructions, and forms in Q-Pulse, and where required in manuals, which are specific to work areas.*
- *Documents, including records & data, determined by the department to be necessary to ensure the effective operation and control of its processes.*

The documented information required by the standard BS EN ISO 9001:2015 is supported by this Quality Manual and the procedures within Q-Pulse.

7.5.2 Creating and updating

The processes for the creating and updating of documents and data are as follows:

***OCC-QS-L2-003** Document and Data Control provides a process for the control, approval, authorisation and issuing of documents.*

7.5.3 Control of Documented Information

The processes for the control of documents and data are as follows:

Documents and software data required for the operation of the quality management system are controlled following **OCC-QS-L2-003** Document and Data Control. The procedure ensures that:

- Documents are approved for adequacy prior to release.
- Documents are reviewed, updated as necessary and re-approved.
- Relevant latest issue versions of documents are available to all staff where activities essential to the effective functioning of the quality management system are performed.
- Obsolete documents are removed from all points of issue and use.
- Any obsolete documents retained for legal or knowledge preservation purposes are suitably identified and controlled.
- Current and Obsolete Documents remain legible, uniquely identifiable and retrievable.
- A document master register held electronically within Q-Pulse identifies the current revision status of documents including applicable documents of external origin.

OCC-QS-L2-008 Control of Quality Records is maintained to demonstrate conformance with the requirements and effective operation of the quality management system. The procedure establishes and maintains identification, storage, retrieval, protection, retention time, and disposition of quality records.

OCC-QS-L2-006 *Complaints, Non-Conformance and Corrective Action incorporates the recording, monitoring and assessment of Incidents, and Non-conformities using Q-Pulse and details the use of the Trust's DATIX system within the department. All incidents are reviewed at the appropriate Governance meeting.*

OCC-QS-L4-005*, List of Quality Records, outlines the guardian and retention periods for quality records. Not withstanding these, all radiation related records are kept for the periods recommended in Appendix 9 of the Medical and Dental Guidance Notes, IPEM, 2002.*

Documented aspects of treatment care are maintained within the hardcopy hospital patient Oncology record and those aspects pertinent to radiation therapy are held in digital format within ARIA RadOnc.

8 OPERATION

8.1 Operational planning and control

The *radiotherapy* management team have determined, planned, documented and implemented the processes necessary to realise required patient care services consistent with the quality policy, objectives and planning. These processes are operated under controlled conditions to meet customer/patient requirements *and will be part of the quality objectives for the service in the Radiotherapy Development Plan*
In planning to realise patient care services; the Radiotherapy Head of Service determines that:

- Quality Objectives for the service are communicated to staff.
- Processes for controlling the services are established and the required resources recorded on computer and hardcopy.
- Verification and validation activities and the criteria for acceptability are established and communicated to patients, who are then asked to comment by the Patient Feedback Questionnaire on *the department*'s performance.
- Records are maintained to demonstrate conformity.

Any outsourced processes required are initiated and monitored via the OUH Trust and are therefore outside of the control of this quality management system.

8.2 Determination of requirements for products and services

8.2.1 Customer communication

The Department provides patients with *verbal and written* information relating to the scope and type of treatment; the rationale behind, and possible side effects of, recommended treatment and the method of administering such treatment. The obtaining of consent documents that patients have received information regarding treatment (see **OCC-CL-L2-003** Patient Consent).
Customer responses to service performance are recorded and actioned through measurement, analysis and improvement procedures described later.
Levels of activity / service are agreed with commissioners.

Patient satisfaction surveys are regularly performed and reviewed by the Management Team. These may be circulated within the Directorate Matron's report. Actions to improve the service are taken where appropriate and decisions documented.

Patient information leaflets are available for treatment procedures via the OUH Internet and provided for patients when attending an appropriate clinic. Patients are encouraged to seek further advice and details from staff on a personal basis.

All customer complaints are responded to in a timely manner in accordance with OUH Policy.

8.2.2 Determination of requirements related to products and services

The Department's requirements for the necessary services to provide patient care are identified and agreed regularly, and include:

- Understanding both the commissioners' and patients' requirements.
- Understanding *the department's* obligations applicable to the regulatory and legal requirements of the NHS and the Trust.
- Any additional *specific* requirements for patients considered necessary by *the Department*.

8.2.3 Review of requirements related to products *and services*

Patient requirements are always agreed with the patient and reviewed by designated staff in Oncology to ensure that they are clearly defined and within the delivery capability of *the Department*.

The results of the review and any modification of patient requirements are recorded as specified in the operational process procedures and maintained in accordance with procedure **OCC-QS-L2-008** Control of Quality Records.

To ensure that equipment required for the delivery of radiation treatment to patients is maintained in a state fit for purpose, the department has a Managed Equipment Service with appropriate contracts are placed with the manufacturers. Such contracts are routinely monitored and reviewed by both the Department and Contractor to ensure that the agreed requirements are met.

8.3 Design and development *of products and services*

8.3.1 General

The Department plans and controls design and development of all aspects of the service.

The Department keeps abreast of current trends and techniques by attending external study days, journal club, multi-disciplinary and other professional meetings.

These are reviewed and updated to comply with legislative updates. Changes in work practice, purchase of new equipment etc are implemented by Focus Work Groups following ***OCC-QS-L2-012*** *Change in Practice and Implementing New Techniques.*

8.3.2 Design and development planning

For new developments within the department, the Radiotherapy Development plan, supported by the use of New Proposal documentation, is used to facilitate efficient implementation, ensure effective service realisation is achieved *and ensure appropriate commissioning is undertaken*.

Clinical Oncologists plan and approve the design and development of all patient treatments following the clinical protocols documented within the Quality System.

Patient treatment planning is controlled through:

- The development of an individual treatment plan to provide the most appropriate treatment for the patient
- Liaison with the Consultant to provide clinical input to the treatment plan.
- Review, verification and validation activities appropriate for each design and development stage.
- Establishing the responsibilities and authorities for design and development activities between the different staff groups.

It is the responsibility of the Radiotherapy Head of Service to ensure that the interfaces between Oncology staff, the Consultants and Radiotherapy Physics function effectively so that responsibilities are always fully understood and in the best interests of the patient.

8.3.3 Design and development inputs

The department controls design and development inputs to ensure new processes are commissioned considering the performance needs, information from previous activities, and statutory & legislative requirements, considering the potential consequence of failure during development. Commissioning programmes are developed and completed where new radiation equipment is required.

With respect to patient treatments, a Treatment Plan[1] will contain:

- Specific information about the patient's requirements.

[1] "Treatment plan" may be radiotherapy, or any other treatment prescribed by a Clinical Oncologist/ deputy

- Detailed prescription of any therapy required authorised by an appropriate clinician in accordance with *Department* protocols and procedures.
- Information provided by recognised suppliers to support treatment delivery as prescribed
- Other information essential for the patient's care

It is the responsibility of Oncology Staff to resolve any incomplete, ambiguous or conflicting requirements with both the patient and their Consultant as their treatment and care progresses

Clinical Protocols have been developed, with input from different professional groups within and outside the Hospital:

- *Clinicians*
- *National and International Standards*
- *Statutory/Regulatory bodies*
- *Hospital Staff e.g. IT Project Group*
- *Departmental staff - clinical and administrative*

8.3.4 Design and development controls

The desired results of changes to the quality system are defined at the outset and, following implementation, monitored to ensure that the requirements have been met – see radiotherapy development plan and commissioning programme where required for specific projects.

All changes to *a* patient's treatment plan during their course of treatment in *the department* will be discussed with the Consultant and the patient as appropriate by staff. All such changes will be recorded in the Treatment Sheet and/or in Aria as required.

8.3.5 Design and development outputs

The department will review the outputs to ensure the intended outcome has been achieved – see Radiotherapy development plan and completed commissioning programmes where required.

*All changes to procedures are first agreed by the appropriate Head of Section/Clinical Lead prior to being communicated to staff as soon as practicable. Documented procedures are updated and controlled via Q-Pulse (**OCC-QS-L2-003** Document and Data Control).*

Radiotherapy Treatment plans will be recorded in electronic format within Aria to ensure that:

- The proposed plan has been checked against the Clinician's patient treatment prescription and is feasible and realistic
- The details of the treatment plan may be referred to by *department* staff as required
- Key stages of the patient's progress are clearly documented and can be measured during the patient's course of treatment in *the department.*
- Legal requirements regarding record keeping are met

Treatment Plans will be made available for review by the patient's Consultant when preparation is complete prior to treatment taking place.

8.3.6 Design and development changes

All new or updated procedures are monitored with regard to their impact on service provision and to ensure that they conform to specified requirements and are commissioned appropriately. Such changes are documented within Q-Pulse.

All changes to the patient's treatment plan during their course of treatment in *the department* will be discussed with the Consultant *(or their covering colleague)* and the patient as appropriate by staff. All such changes will be recorded in the Treatment Sheet and/or in Aria as required.

8.4 Control of externally provided products and services

8.4.1 General

Products and services are purchased internally within the Trust or from external suppliers in accordance with the provisions and requirements of the Trust's Standing Financial Instructions (SFI).

8.4.2 Type and extent of control of external provision

Suppliers of products or services that can affect the quality of service are evaluated and selected based on their ability to supply in accordance with specified requirements. Evaluation, periodic re-evaluation and selection processes are undertaken in liaison with OUH Procurement policies.

Where suppliers of products or services fail to meet the standards required, non-conformances are raised and monitored through DATIX and the matter resolved where possible by mutual agreement.

*Acceptance tests are performed to check the performance of capital equipment against the manufacturer's specifications prior to clinical use (**OCC-PDS-L2-002** Acceptance and Commissioning of Machines and Equipment).*

8.4.3 Information for external providers

The Trust's Standing Financial Instructions (SFI) require that information clearly describing the product or service ordered is recorded on a Requisition/Purchase Order *electronically ordered via Oracle,* and verified prior to release. *Documented information is provided to the external provider describing,* where appropriate*:*

- *the goods and services to be provided or the process to be performed;*
- *the requirements for approval or release of goods and services, procedures, processes or equipment;*
- *the requirements for competence of personnel, including necessary qualification;*
- *the quality management system requirements;*
- *the control and monitoring of the external provider's performance to be applied;*
- *the requirements for handling of external provider's property;*
- *health and safety policies to be observed by external providers when working on the OUH site.*

The relevant Head of Department in liaison with OUH procurement will ensure the adequacy of specified requirements prior to their communication to the external provider.

The Departments monitor the performance of external providers and document information describing the results of such monitoring.

Verification of purchased product or service is undertaken according to the Trust's SFI.

8.5 Production and service provision

8.5.1 Control of production and service provision

The provision of all patient care and support services by Oncology are planned and carried out under controlled conditions defined in operational procedures that specify the availability of:

- information and support for users *i.e. staff training & competency, patient information & support services;*
- procedures, *work instructions, and* related documentation;
- the use of any operational or measuring equipment;
- monitoring and verification activities, *e.g. equipment and/or treatment plan quality control, patient side-effects and risks associated with the activities;*
- documentation including referral forms, letters, records, etc.

The effectiveness of the Consultant's prescription for patient treatments will be tested by periodic clinical audit within the Hospital and by discussions with purchasers. Where those processes of patient care are within the control of *department* staff, regular validation of processes take place including, as applicable:

- *effectiveness* of the Department's processes;
- *suitability* of equipment and personnel;

- use of defined methodologies and procedures within the quality management system;
- requirements for records;
- re-validation by discussions with Consultants and patients *and purchasers*.

The results of such validation will be discussed in accordance with procedure **OCC-QS-L2-001** Management Review. Patient feedback may be obtained.

8.5.2 Identification and traceability

Patients details are logged on the Trust's EPR computer system and within Aria *RadOnc*. All documents *and products* relating to patients, *that are used, created, or filed*, are identified *with the patient's name and* NHS number *as a minimum; their OUH Trust number may also be added This includes electronic records, treatment prescription forms, case notes, treatment plans, immobilisation aids, and beam modification devices.*

*Prior to any planning or treatment procedure being conducted, the patient's identity must be confirmed in accordance with **OCC-RT-L3-019** External Beam Radiotherapy and HDR Brachytherapy – Patient Identification Procedure or for therapeutic isotope treatments, the radiology patient identification process is followed.*

Similarly, quality control of equipment is recorded for all aspects that may reflect the suitability of equipment to meet the required standards of reliability and accuracy.

8.5.3 Property belonging to customers *or external providers*

Patient property left in *in the department* following discharge is stored and maintained in accordance with current Trust policies.

Staff working within the department complete the Trust's Information Governance training annually, which supports the Trust policy and defines the way we use information effectively and appropriately, safeguarding patient confidentiality, and integrity. It encompasses the requirements of the Data Protection Act 1998, Information Security Management, The Confidentiality Code of Practice, and Records Management.

*Maintenance contracts are directed towards ensuring that the necessary services maintain or enhance the performance, availability and quality of the service the department provides. Contractors providing on-site service for the equipment are supported by department processes (**OCC-PDS-L2-002** Acceptance and Commissioning of Machines and Equipment) and OUH Health and Safety policies. When working in radiation controlled areas, formal handover procedures are performed and contractors work within their own schemes of work.*

8.5.4 Preservation

Patient care is the responsibility of all members of the department. Staff are responsible for making the patient feel at ease in the hospital environment, providing them with written and oral communication about their treatment and possible side effects, reassuring them at all stages of treatment and being sensitive to their social and psychological needs.

*A routine quality assurance programme is in place as recommended by national and international bodies and required by Regulation; to ensure the equipment is safe to use for patient treatment, and that it is maintained such that all the machine parameters are within the range defined during the "machine acceptance" (**OCC-PDS-L2-003** Routine testing of Machines and Equipment, **OCC-PB-L3-005** Prostate Seed Brachytherapy, Routine Equipment QA).*

Control of radioactive materials are in accordance with our Environment Agency permits as documented in our Radiation Protection Manual.

8.5.5 Post-delivery activities

Patient care both post treatment and post examination are paramount and form part of our patient care pathways. All care episodes are documented and where appropriate handed over to external healthcare individuals. Follow up appointments are managed in accordance with the patient's wishes paying heed to their social and psychological needs.

The management of radioactive waste is governed by Environment Agency permits and carefully controlled and monitored as per procedures documented in the Radiopharmacy Manual (external to the Radiotherapy Dept. Quality System).

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8.5.6 Control of changes

Where change is required, either planned or unplanned, such changes are implemented in accordance with ***OCC-QS-L2-012*** *Change in Practice and Implementing New Techniques, and documented within Q-Pulse. Records of changes are also maintained within Q-Pulse.*

Where a temporary change in practice is required, e.g. a dose variation from the standard protocol due to a patient's specific condition, a concession form will be raised and granted (see ***OCC-QS-L2-007*** *Concessions)*

8.6 Release of products and services

Acceptance criteria at key stages of the provision of care and support services to patients are monitored and recorded routinely as part of the operational process to verify conformance with specified requirements of the services. *Authority for release of services to the next stage of any process is recorded. Where new or significantly altered products or services are released these are controlled within the quality system and may involve a New Proposal Form submission to support the development.*

8.7 Control of nonconforming outputs

Any occurrence of non-conformance *related to the Quality System* is identified, recorded, and reviewed as part of one of the following procedures:

OCC-QS-L3-001 *Incident Policy*

OCC-QS-L2-006 Complaints, Non-conformances and Corrective Action

OCC-QS-L2-007 Concessions

Patient complaints are processed through the Trust's Patients Complaints Procedure.

Non-conformance is reviewed and acted upon by designated members of staff with the requisite responsibility and authority, in accordance with **OCC-QS-L2-001** Management Review. *Documented evidence is maintained of the nature of the non-conformance, the actions taken, the outcome and the persons involved in the processes.*

9 PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The Department has defined, planned, and implemented measurement, monitoring, analysis and improvement processes to ensure that the quality management system, processes, and services conform to specified requirements. Monitoring applies to patient care outcomes, patient satisfaction, equipment reliability, support services, environment and facility conditions. These processes are operated under controlled conditions and are described in the following sections.

9.1.2 Customer satisfaction

The Department monitors *patient/*customer satisfaction using the following methods:

- Reviewing 'thank you' cards etc given to the treatment units
- Feedback on completion of external beam radiotherapy (Patient Feedback Questionnaires)
- *OUH 'Please Tell Us' feedback forms*
- Information from local responses to national cancer patient satisfaction surveys.
- *Feedback from discussions with purchasers.*
- *Monitoring equipment reliability and service effects.*
- *Meetings between the various Department staff groups, including 'Listening into Action'*
- *Staff satisfaction surveys (conducted by the Trust)*
- Customer complaints recorded as part of procedure **OCC-QS-L2-006 Complaints, Non-conformances, Corrective and Preventive Action.**

The results of all customer satisfaction *feedback* are recorded, analysed and evaluated for potential opportunities for improvement, and reported to the Radiotherapy Service Clinical Governance meetings. *These may also be reported within the Oncology & Haematology Matron's monthly report, presented at the Divisional Governance meeting.*

9.1.3 Analysis *and evaluation*

*The efficiency and effectiveness of the Department's processes are regularly measured and monitored (**OCC-QS-L2-001** Management Review and **OCC-QS-L2-009** Internal Quality Audit). Results are used to determine whether patient/customer requirements are being met and to demonstrate the continuing ability of the processes to satisfy their intended purposes. Monitoring is also used to seek out potential opportunities for process improvement.*

Data is collected and analysed to determine the effectiveness of the quality management system and to identify where improvements can be made (***OCC-QS-L2-001*** Management Review)

Relevant data includes *but are not limited to:*

- *Patient/*customer satisfaction/dissatisfaction.
- *Department activity statistics.*
- *Equipment and dosimetry quality assurance.*
- *Machine stability and Uptime.*
- *Clinical Audit.*
- Conformance to customer requirements.
- Non conformance reporting
- Incident Reporting also using the Datix trust wide incident reporting system.

9.2 Internal Audit

The Department carries out objective audits by appropriately trained personnel to determine whether the quality management system has been effectively implemented and maintained, and conforms to the ISO 9001:20*15* standard. Management ensures that timely corrective action is taken to address any deficiencies found and follow-up action will be taken and reported. The audits are also used to seek out potential opportunities for improvement. The audit process and resources are specified in procedure **OCC-QS-L2-009** Internal Quality Audit**.**

In compliance with national standards and guidance we are actively engaged in external audit by peer review of aspects pertaining to radiation dosimetry.

9.3 Management review

Management Review takes place on a monthly basis within the Radiotherapy Clinical Governance meeting to enable the management team to regularly review the quality management system to ensure its continuing suitability, adequacy and effectiveness. The review also evaluates the need for changes to the quality management system, including policy and objectives.
The business strategic direction of the organisation and especially cancer services underpin the objectives of the Department and are considered as part of management review.

An agenda within **OCC-QS-L2-001 Management Review** ensures the following are included for review:

- Follow-up actions from previous management review reports/ minutes.
- *Organisational Knowledge and factors affecting the strategic development of the department.*
- Results of internal and external audits.
- Management Review Report.
- Customer feedback (commendations / complaints).
- Process performance *including review of the Radiotherapy Development plan (departmental objectives) and Trust objectives.*
- Status of corrective actions and identification of any trends in NCRs.
- Review of any Incidents within the Radiotherapy service.
- Training needs *and future plans.*
- Changes that could affect the quality management system.
- *Review of Infrastructure and Work Environment.*
- Recommendations for improvement,
- *Review of the Quality Policy for the department.*

Minutes are prepared and retained *and* actions *to be undertaken detailed. These are circulated to the members of the Radiotherapy Clinical Governance meeting and other appropriate people as necessary.*

10 IMPROVEMENT

10.1 General

The Department operates procedure **OCC-QS-L2-001** Management Review that describes the use of the quality policy, objectives, internal audit results, analysis of data, corrective and preventive action, and Management Review to facilitate continual improvement of the quality management system.

10.2 Nonconformity and corrective action

*Failures in the system are addressed in a timely manner with an emphasis placed on reducing or eliminating the causes of nonconformity in order to prevent recurrence (**OCC-QS-L2-006** Complaints, Non-conformances, and Corrective Action).*

10.3 Continual improvement

The current and future needs and expectations of patients and the requirements for achieving customer confidence are agreed in contracts with Commissioners, individual patients and other healthcare providers.

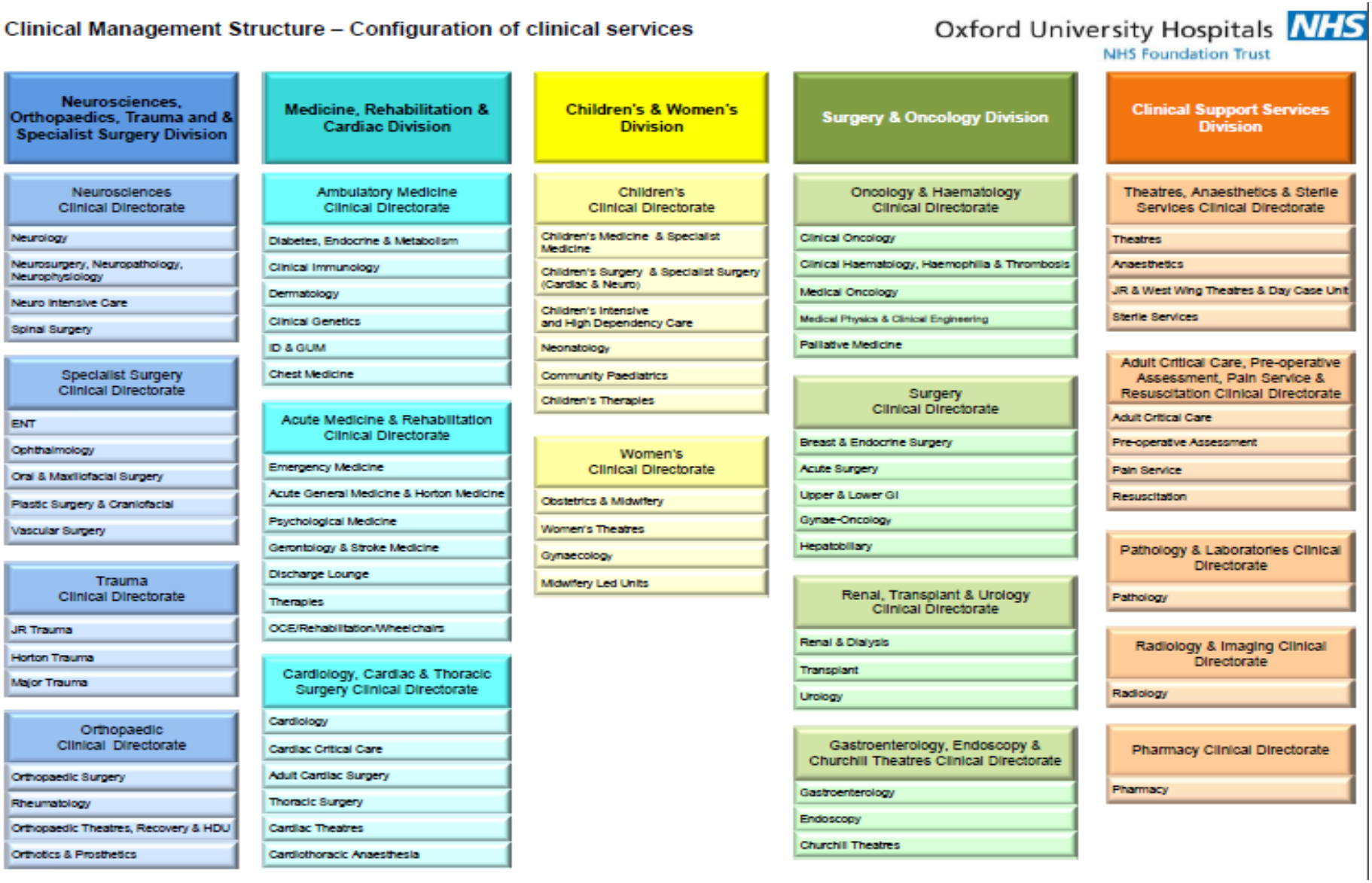
The Department establishes the needs and expectations of their patients/customers by regular liaison with purchasers and other healthcare providers.

The Department will be responsive to the needs of patients and their carers at all times. Patient Satisfaction Surveys are regularly completed and analysed to assess levels of patient satisfaction and address any deficiencies that arise.

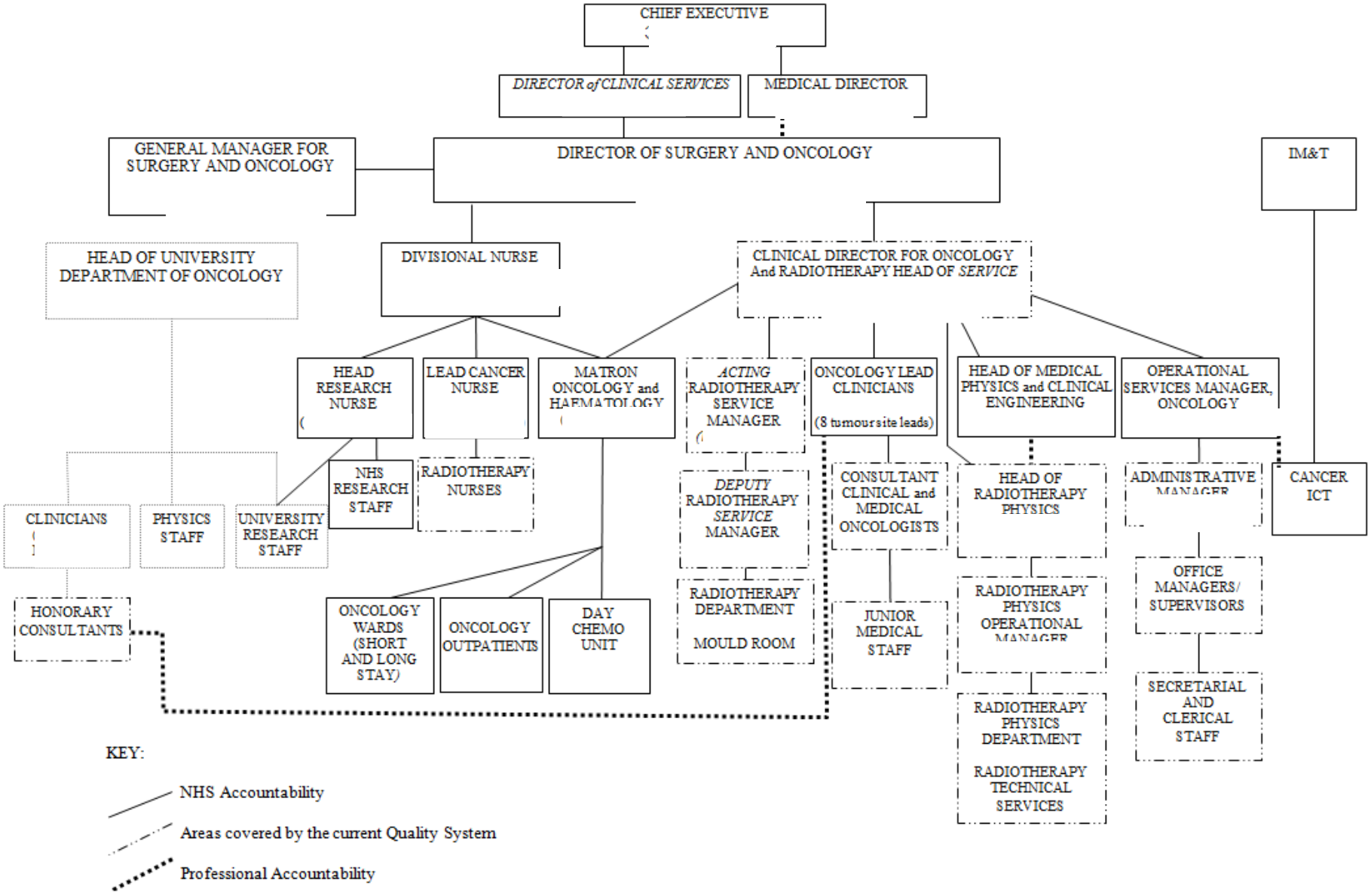
The processes for meeting patient/customer requirements are communicated to all staff in the Departments and are continually evaluated for improvement. Regular staff meetings are held for staff groups across the Department to discuss patient and other issues.

OXFORD CANCER CENTRE

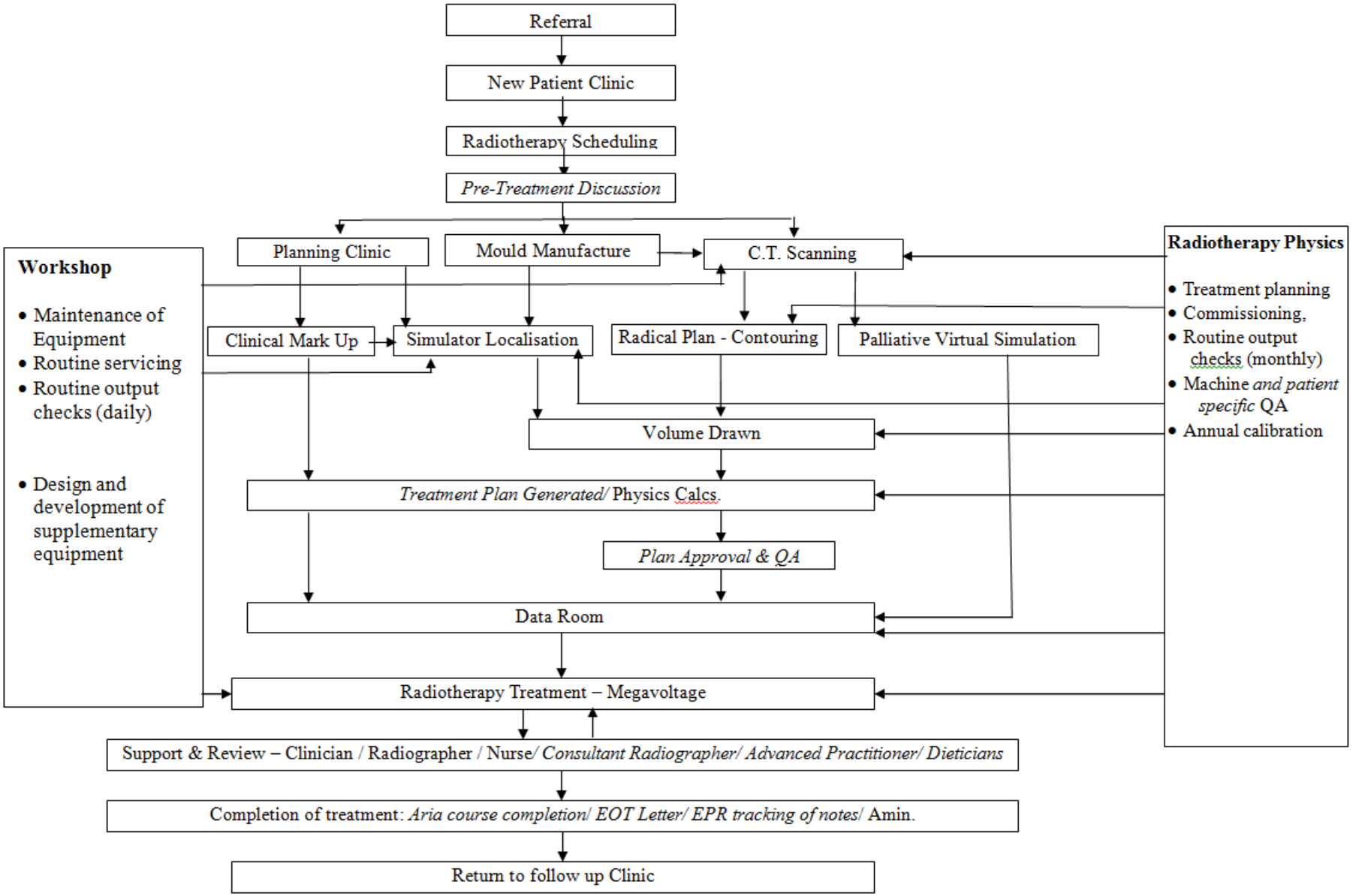
APPENDIX 2:


Clinical Management Structure – Configuration of clinical services
Oxford University Hospitals NHS
NHS Foundation Trust
Neurosciences, Orthopaedics, Trauma and & Specialist Surgery Division
Neurosciences Clinical Directorate
Neurology
Neurosurgery, Neuropathology, Neurophysiology
Neuro Intensive Care
Spinal Surgery
Specialist Surgery Clinical Directorate
ENT
Ophthalmology
Oral & Maxillofacial Surgery
Plastic Surgery & Craniofacial
Vascular Surgery
Trauma Clinical Directorate
JR Trauma
Horton Trauma
Major Trauma
Orthopaedic Clinical Directorate
Orthopaedic Surgery
Rheumatology
Orthopaedic Theatres, Recovery & HDU
Orthotics & Prosthetics
Medicine, Rehabilitation & Cardiac Division
Ambulatory Medicine Clinical Directorate
Diabetes, Endocrine & Metabolism
Clinical Immunology
Dermatology
Clinical Genetics
ID & GUM
Chest Medicine
Acute Medicine & Rehabilitation Clinical Directorate
Emergency Medicine
Acute General Medicine & Horton Medicine
Psychological Medicine
Gerontology & Stroke Medicine
Discharge Lounge
Therapies
OCE/Rehabilitation/Wheelchairs
Cardiology, Cardiac & Thoracic Surgery Clinical Directorate
Cardiology
Cardiac Critical Care
Adult Cardiac Surgery
Thoracic Surgery
Cardiac Theatres
Cardiothoracic Anaesthesia
Children's & Women's Division
Children's Clinical Directorate
Children's Medicine & Specialist Medicine
Children's Surgery & Specialist Surgery (Cardiac & Neuro)
Children's Intensive and High Dependency Care
Neonatology
Community Paediatrics
Children's Therapies
Women's Clinical Directorate
Obstetrics & Midwifery
Women's Theatres
Gynaecology
Midwifery Led Units
Surgery & Oncology Division
Oncology & Haematology Clinical Directorate
Clinical Oncology
Clinical Haematology, Haemophilia & Thrombosis
Medical Oncology
Medical Physics & Clinical Engineering
Palliative Medicine
Surgery Clinical Directorate
Breast & Endocrine Surgery
Acute Surgery
Upper & Lower GI
Gynae-Oncology
Hepatobiliary
Renal, Transplant & Urology Clinical Directorate
Renal & Dialysis
Transplant
Urology
Gastroenterology, Endoscopy & Churchill Theatres Clinical Directorate
Gastroenterology
Endoscopy
Churchill Theatres
Clinical Support Services Division
Theatres, Anaesthetics & Sterile Services Clinical Directorate
Theatres
Anaesthetics
JR & West Wing Theatres & Day Case Unit
Sterile Services
Adult Critical Care, Pre-operative Assessment, Pain Service & Resuscitation Clinical Directorate
Adult Critical Care
Pre-operative Assessment
Pain Service
Resuscitation
Pathology & Laboratories Clinical Directorate
Pathology
Radiology & Imaging Clinical Directorate
Radiology
Pharmacy Clinical Directorate
Pharmacy

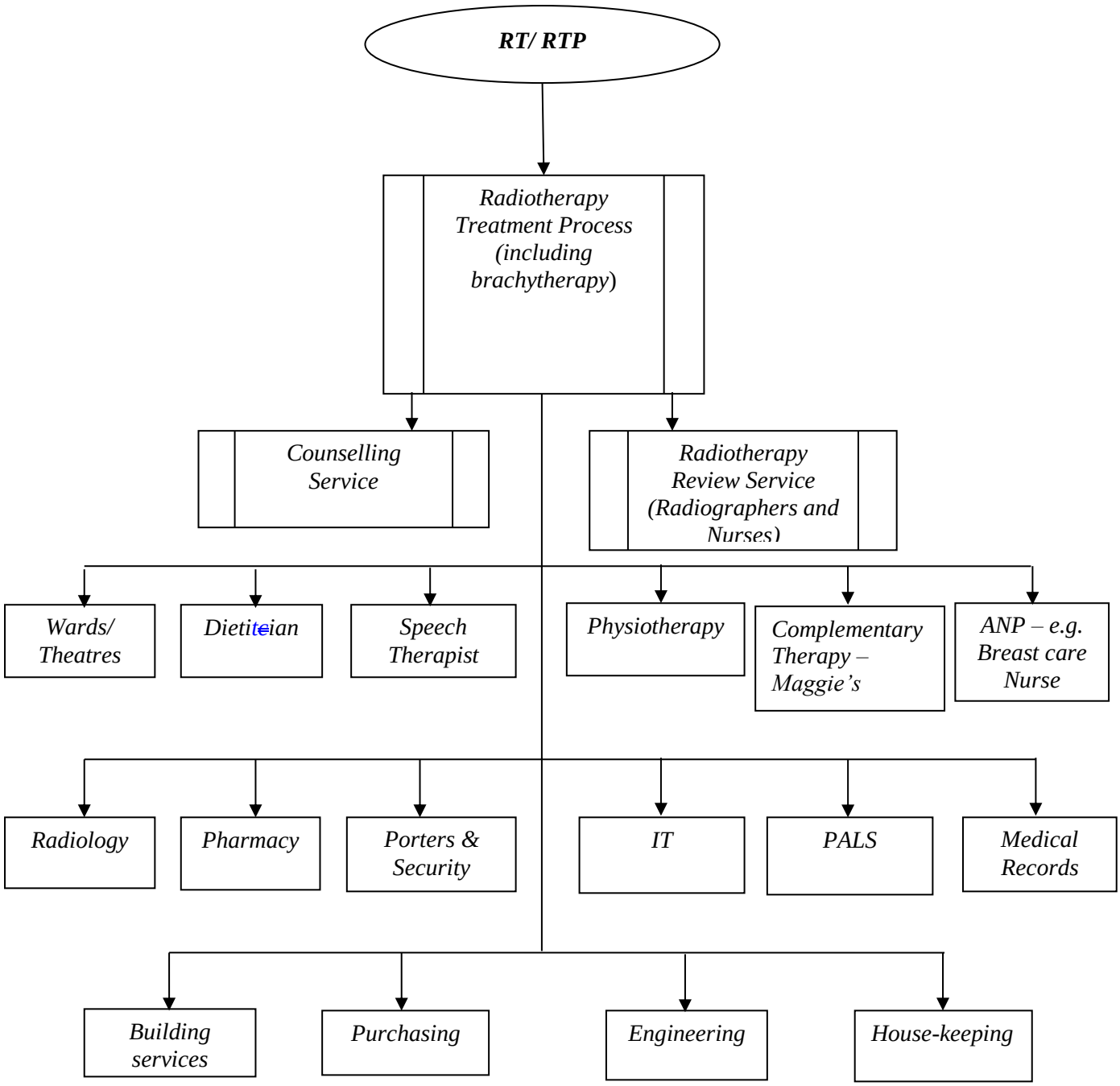
APPENDIX 3: OUH Lines of Managerial Accountability for Oncology Staff



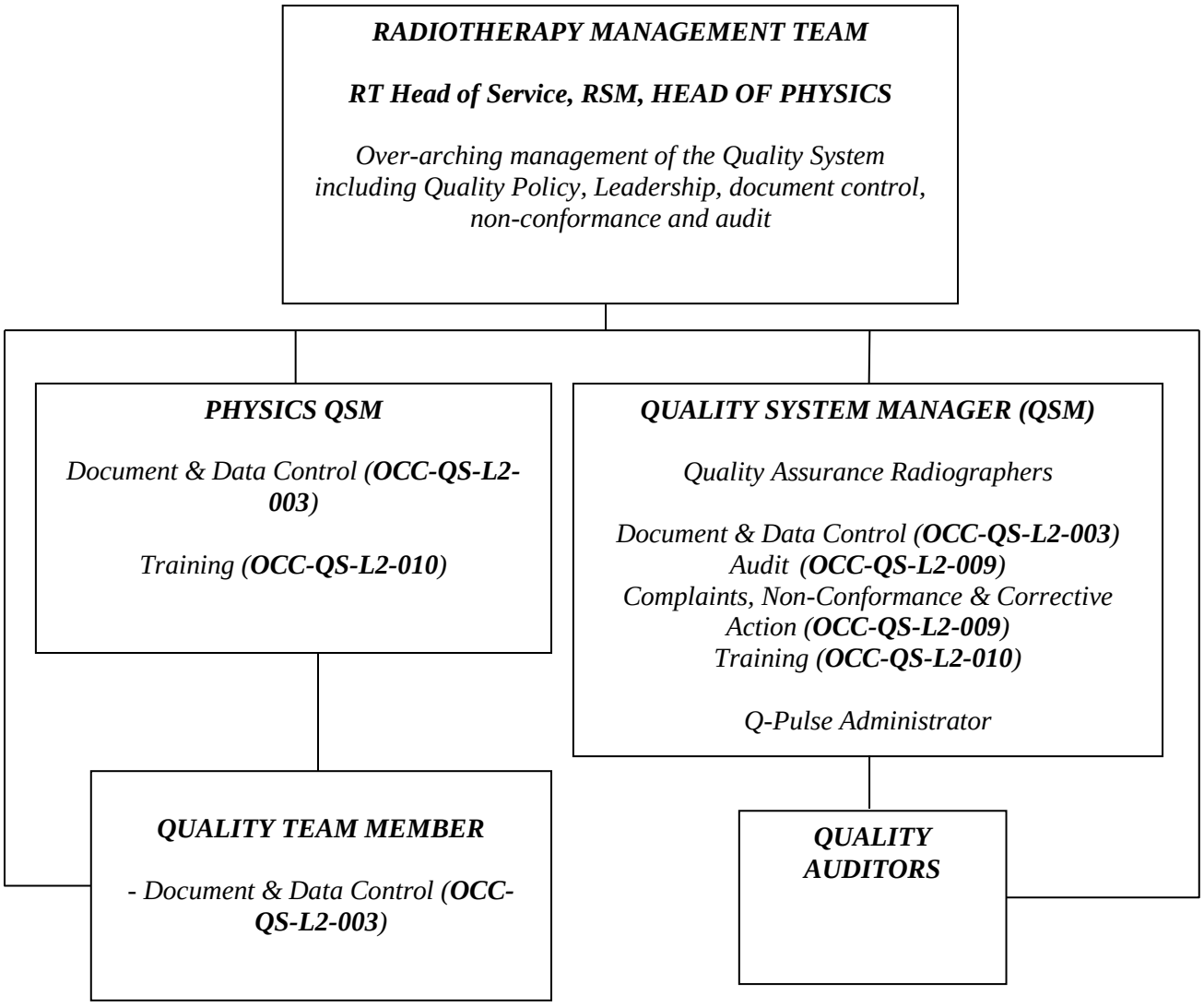
APPENDIX 4: Radiotherapy Treatment Process



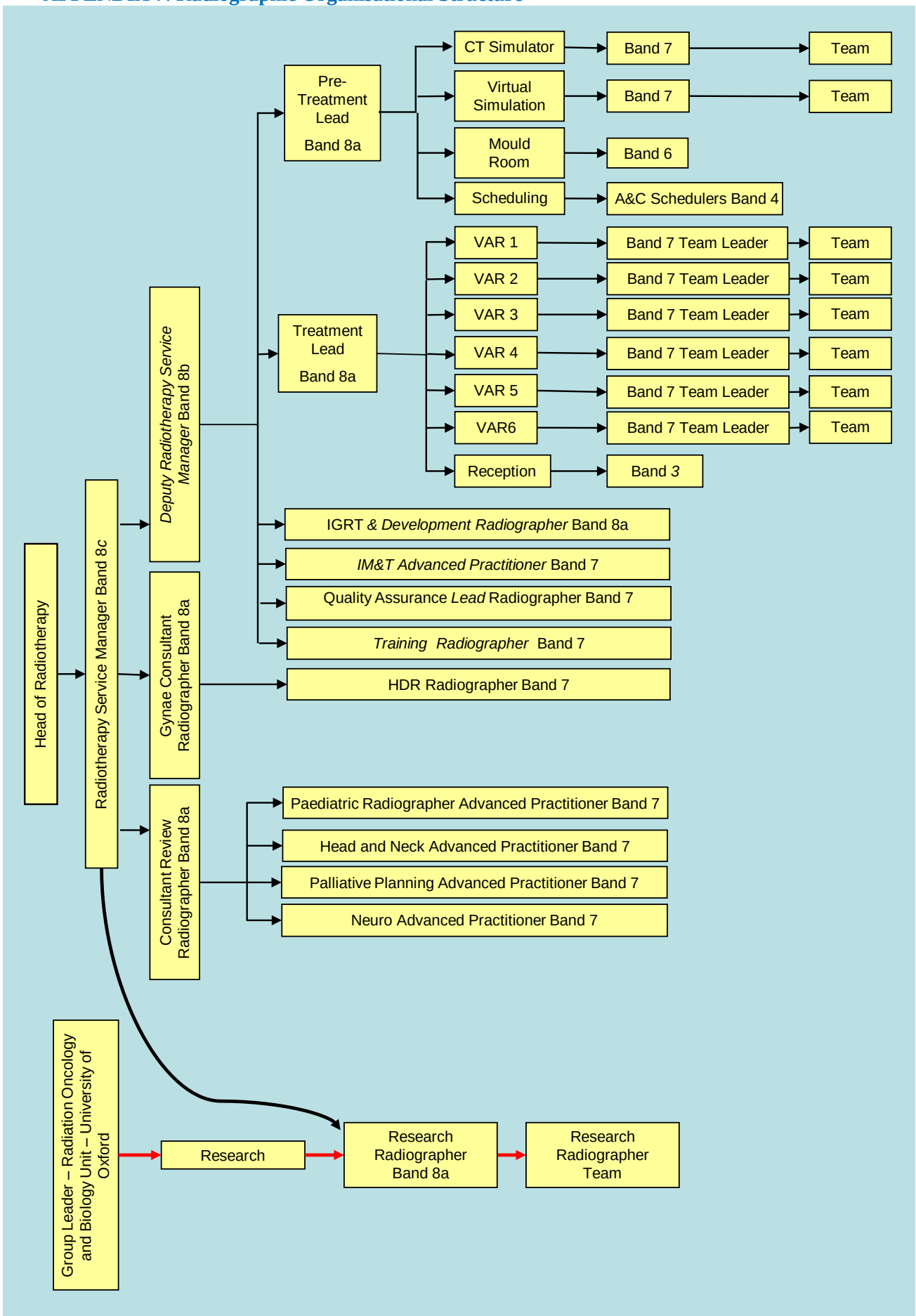
APPENDIX 5: *Radiotherapy Support Services*



APPENDIX 6: ***QART Team – Organisation and Responsibilities***



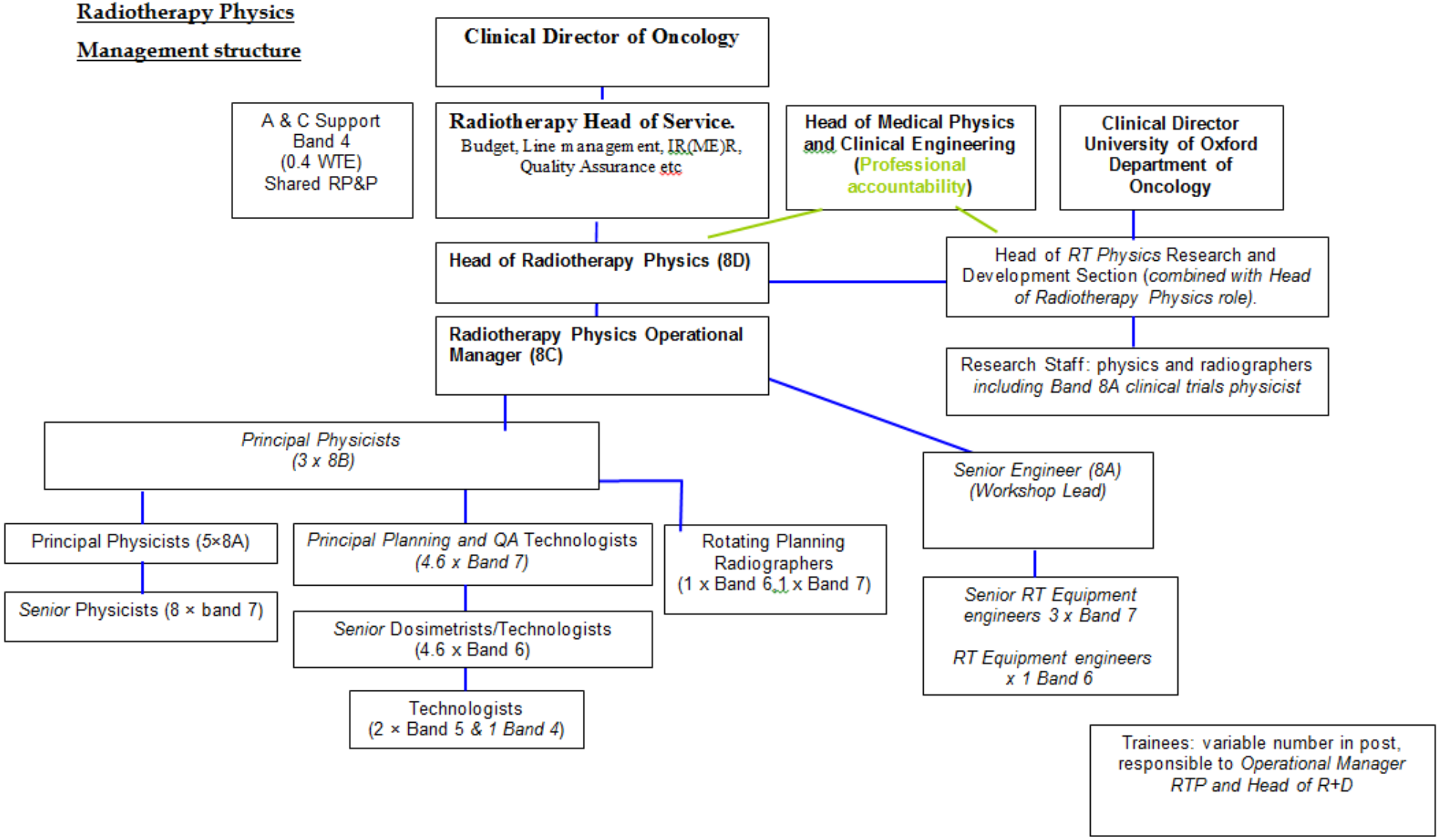
APPENDIX 7: Radiographic Organisational Structure



APPENDIX 8:

Radiotherapy Physics

Management structure



APPENDIX 9: Nuclear Medicine Process flow