New JD

Freedom 5? (3)
No change to band
✓ 23/11/10

Job Description for

Head of Medical Physics Section

ment of Clinical Science and Engineering (CSE)
Salisbury NHS FoundationTrust

Senior Manager, Quality Management, Regulatory and IT

Odstock Medical Ltd

Job Details

Job Title Consultant Clinical Scientist
Head of Medical Physics Section
Senior Manager, Quality Management, Regulatory and IT. (0.4WTE)

A4C Grade Consultant Clinical Scientist 8B

Location Clinical Support and Family Services Directorate,
Salisbury District Hospital

Responsible to:
Professor Ian Swain, Director of Clinical Science and Engineering
& Clinical Director, Odstock Medical Ltd

Job Purpose

To manage, lead and develop high quality and cost effective science and engineering based services, systems and devices to meet the needs of patients and staff within Salisbury NHSFT, nationally and internationally within the strategic aims and objectives of CSE.

To advise, plan and act to ensure compliance with UK legislation, associated regulations and codes of practice to do with the Trust use of ionising and non-ionising radiation. (e.g. Ionising Radiation Regulations 1999, Ionising Radiation (Medical Exposure) Regulations 2000)

To instigate, manage and continuously improve, externally audited Quality Management systems to enable the manufacture and sale of medical devices in Europe and other territories. This involves compliance with the regulatory requirements of the European Medical Devices Directive and other specific standards for supply to the NHS plus additional international compliance regimes for other territories (presently including USA & Canada). Management of compliance requirements may be in house or externally contracted.

To manage IT requirements for server based network (25+ user) with patient booking and manufacturing operations support. To liaise with Trust IT for CS&E IT development.

To manage the personnel, finance, service development, and training within Medical Physics Section. To participate at a senior management level in the planning and strategy of CSE. To ensure the interests of CSE and Salisbury Healthcare NHS Trust are represented and promoted at local, national and international level.

To provide scientific and technical input and support to device and product development.

To undertake secondment to Odstock Medical Ltd (currently 0.4w.t.e) in the senior management role of Quality and IT manager. This encompasses medical device regulation and approval for the OML stimulator range for a number of territories and IT management via a 3rd party support company.

Scope of the Job

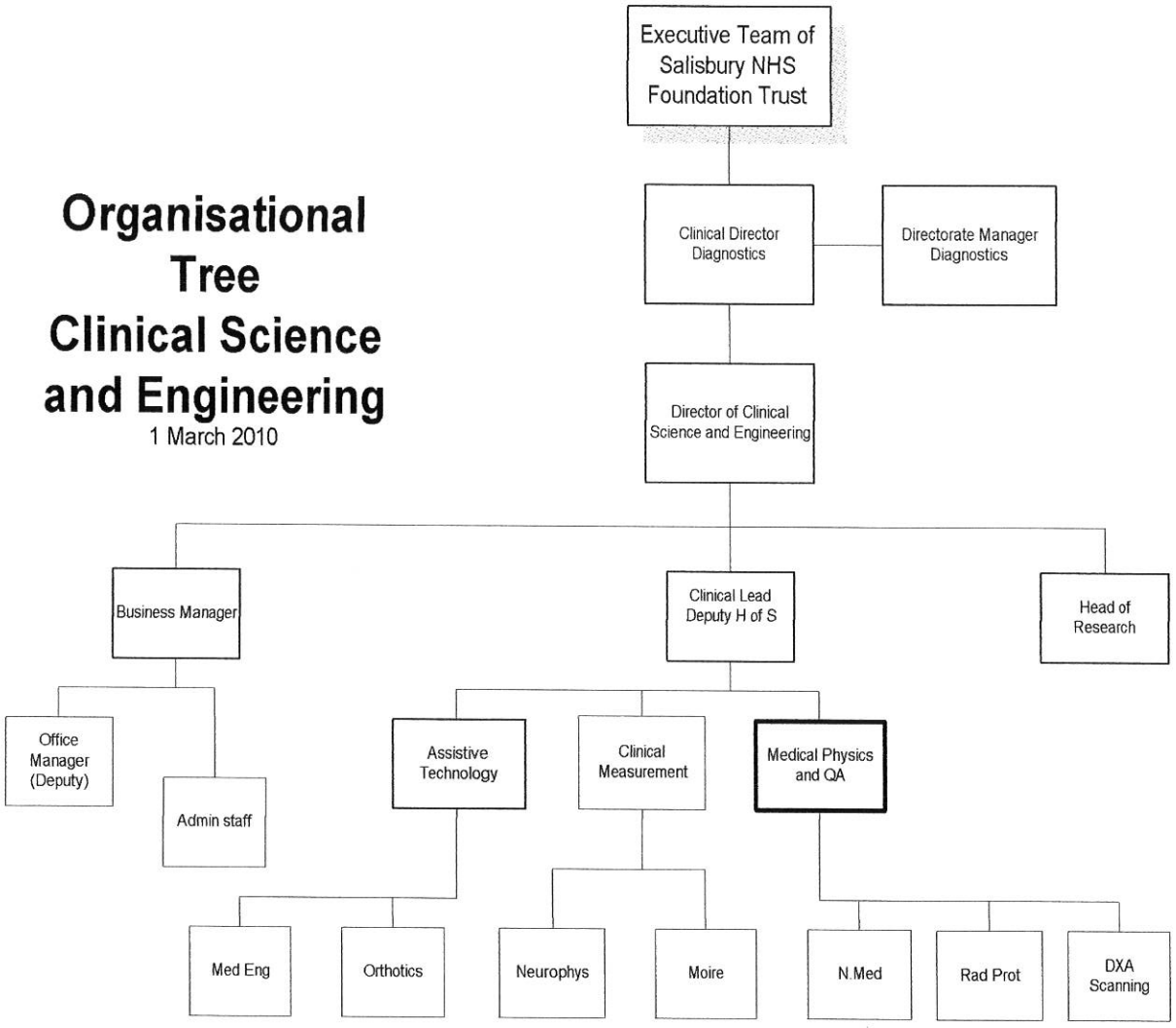
To manage the Medical Physics Section within CSE, participating in the CSE Strategic Management Group to influence and advise on Medical Physics operations plus CSE Quality Management and IT. To deliver advice, planning and action for changes in national and international quality management, regulatory and legislative requirements as they affect the operation of CSE, OML and SNHSFT. To support SNHSFT management with expert advice where the postholder has the appropriate physics and engineering expertise.

Dimensions

Budget	Spending authority within the Departments budget of ca £1.5M
Staff Numbers	1 Clinical Scientist (8A) directly managed Team of DXA operators (Radiology Assistant practitioners) for their work within the DXA service. (no rotas, sickness etc)
Contracts	Block contract with Wiltshire PCT for DXA Direct GP referrals for Moiré Fringe back shape analysis
Specialties	Quality management Physics Electronics design and development Clinical measurement and functional electrical stimulation
Appointment	Full time NHS with clinical sessions to cover for Department Director in Clinical Measurement and 0.4WTE secondment to OML (see appendix)
Income generation	Maintenance of the ISO13485/ISO9000 quality system and CE marking of medical devices is essential for income generation via sale of medical devices. DXA contract for 240 outpatients per annum Cardiac Nuclear Medicine implemented to serve patients more locally and attract income.

Organisational Tree Clinical Science and Engineering

1 March 2010



Qualification, Skills, Knowledge and Experience

Qualification

Honours degree in Physics.
MSc (required) plus significant experience to PhD level or Ph.D. in a relevant discipline.
State Registered Clinical Scientist.
Corporate Membership of Institute of Physics and Engineering in Medicine (IPEM).

Knowledge

Knowledge and experience in radiation protection and quality assurance of diagnostic x-ray equipment including CT and Mammography (Health and Safety). Knowledge of storage and disposal regulations for radioactive material.
Extensive knowledge of standards, guidance and medical device legislation from implementing and running a quality management system.
In depth knowledge of personal computer hardware and software. Wide and practical knowledge of microcomputer programming and digital electronics.

Skills
People management and document management for QMS and other departmental purposes.
High level of verbal and written communication skills including preparation and delivery of presentations.
Research and development ability.
Demonstrated ability in scientific writing and presentation skills.
Demonstrated ability in teaching.
Acquisition and maintenance of a broad and general appreciation of physical science and engineering outside the hospital environment.

Experience
At least 10 years post training as a Medical Physicist/Clinical Scientist within the NHS.

Post training experience to include radiation protection and quality assurance in a diagnostic radiology environment.

Proven experience in setting up and running an externally verified Quality Management System for compliance with quality standards and medical device regulations for Europe and other countries.

Previous management experience as a Specialty Manager and/or Deputy Head of Service.

Key Tasks

1. To take lead management responsibility for Medical Physics, CSE quality management and IT as agreed with the Department Director and participate in the business planning, future strategic development processes and line management of staff as a member of the CSE. Dept senior management team.

2. To maintain the role of Quality Manager and Management Representative to ensure continued compliance with legislation and standards relating to the manufacture of medical devices produced by the Department. E.g. ISO 13485:2003 registration, MHRA registration and EC Certification. At the same time ensuring that products and services are of the highest quality within financial and other constraints to maintain and extend our business excellence.

3. To ensure prudent financial management and cost effective spending for those areas for which responsibility is delegated by the CSE Department Director.

4. To act as or liaise with the Trust Radiation Protection Advisor as specified in IRR99 in order to manage local radiation policy and radiation protection, radioactive waste disposal and licensing, and other Physics specialties as they may arise. To have a seat on the Radiation Protection Committee (RPC) in order to manage Medical Physics input to the Trusts compliance. The RPC to then feed back through the Risk management and Directorate structure in a timely manner. To become accredited as a Radiation Protection Advisor (RPA) with regard to the above duties.

5. To act as Medical Physics Expert for applicable areas of Diagnostic Radiology, including review of R&D applications which involve the use of ionising radiation.

6. To survey Diagnostic Radiology X-Ray equipment at commissioning and at regular intervals on behalf of the Trust in order to verify safe operation and appropriate image quality within the manufacturer's specifications and legal requirements.

7. To liaise with other departments within the Trust to ensure that appropriate testing and calibration equipment and/or services are in place to comply with legislation and good practice guidelines.

8. To manage the operation, reporting and quality assurance from the DXA scanning service and any similar future outpatient facilities that may fall under Medical Physics.

9. To manage Trust compliance with their Environment Agency Radioactive Waste Disposal Licence and ensure any EA recommendations are implemented.

10. To maintain professional links through local and national specialist meetings and other contacts. To maintain CPD as defined by HPC in order to keep Healthcare Scientist registration

11. To teach, train and supervise Trainee Physicists, Technicians and Undergraduate or Post-graduate Research Students at all levels as required. To educate other staff (including Medical Staff) in specialist areas as required, e.g. Radiation protection, Laser safety etc.

12. To act as Risk Co-ordinator for the Department within Policy Guidelines promulgated by the Trust.

13. To manage the Departmental computing infrastructure including liaison with the Trust IT Department and research and/or commission appropriate applications as may be required. To perform development of bespoke PC and microcontroller software.

14. To participate in and conduct the Department's Research activities. This will require presentations at local, national and international scientific meetings and publication in scientific journals.

15. To apply for and manage Research Grants within the Department and in association with other Institutions. This will include meeting R&D and Ethics Committee requirements and consumer involvement.

16. To undertake clinical measurements within dedicated clinics, on the wards and in the Operating theatre. To act on the findings including prescription of patient aids, advice and reports to referring clinicians. This to include appropriate records and documentation that will permit clinical audit to be taken if required.

17. To act in a consultant capacity to other departments in the Trust on questions of Quality Management where this may have a bearing on Clinical Governance, Controls Assurance or Risk Management etc.

18. To advise the Trust and wider NHS (e.g. NHS Innovation Hub) on other areas of expertise within the field of Medical Physics and Engineering applied to health care.

Communications and Working Relationships

Must have excellent communication skills and be capable of managing and working with all grades of staff within and external to the Trust.

Most Challenging Part of the Job

To set up, manage and maintain the appropriate support for the diverse areas/disciplines associated with the radiation protection, quality system, IT and service delivery requirements within the complex constraints of the Health Service environment.

Conditions of Service

Responsible to:	Director of Clinical Science and Engineering & Clinical Director, Odstock Medical Ltd
Hours	37.5 (at conclusion of A4C transition)
Leave	33 days per annum plus bank holidays.
Salary Scale	Consultant Clinical Scientist profile 8B

Job Description Agreement

This is a true description of the tasks expected of the Medical Physics Section Head within Clinical Science and Engineering.

Dr. Steven Crook
Consultant Clinical Scientist
Clinical Science and Engineering

Date _____

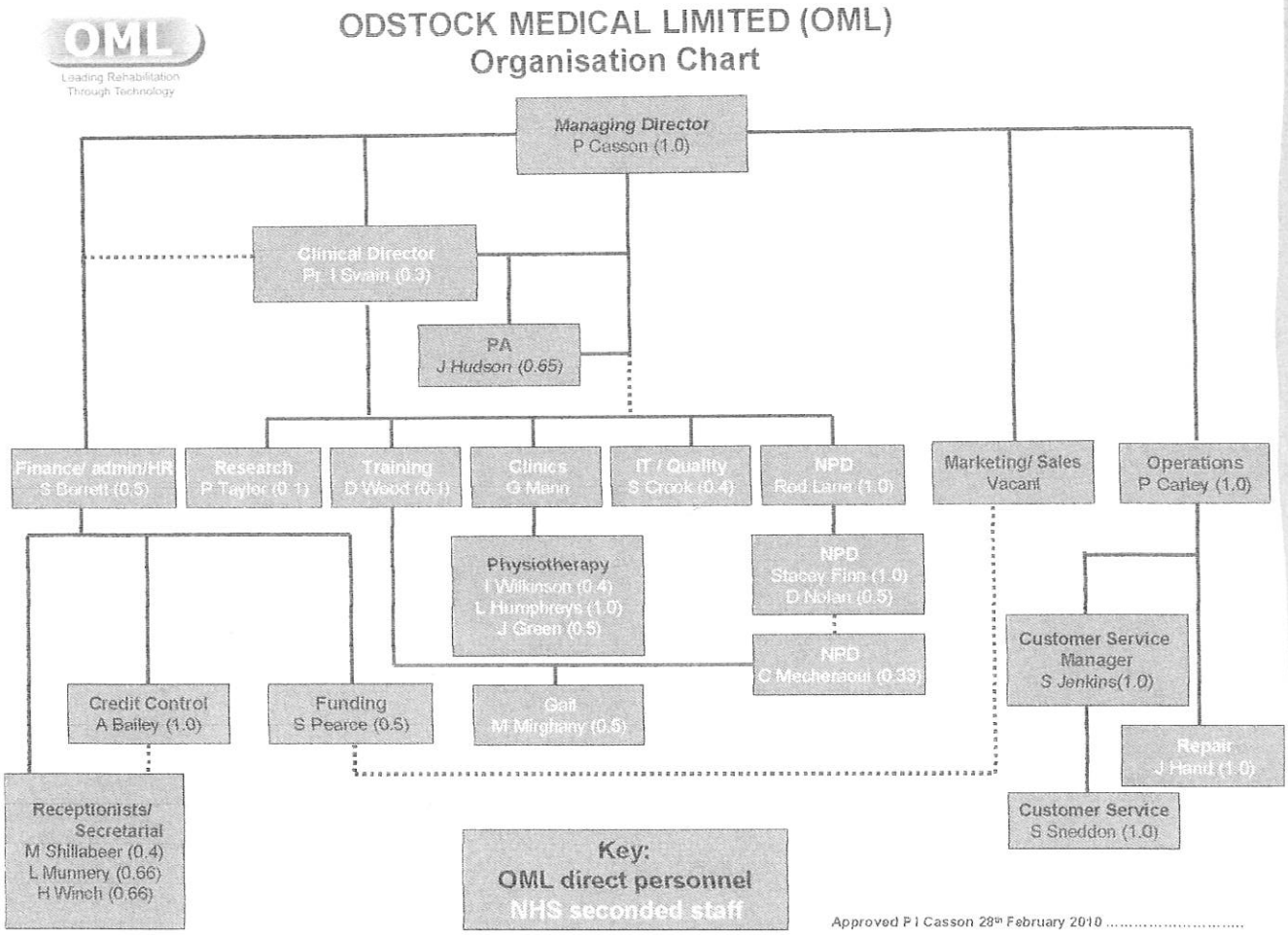
Prof. Ian Swain
Director
Clinical Science and Engineering

Date _____

Appendix

Senior OML Manager – Quality, Regulatory and IT (0.4 WTE)

OML Structure



OML Organisational Chart. N= 25 in post + 1 vacancy. Wte = 15.5

OML Responsibilities

To be a member of the OML senior management team with responsibility for operation and development of the OML Quality Management System, OML compliance with EU and international regulations governing medical devices and management of the OML IT system.

Manage, maintain and improve OML's Quality management system (QMS) to provide compliance to the current version of ISO13485 (Medical devices- Quality management systems – Requirements for regulatory purposes) and FDA Chapter 820. Have the role of Management Representative, liaising with OML's Notified Body (BSI) for BSI Membership, continuing assessment visits, reporting of significant changes and adverse incidents. In conjunction with senior management colleagues, write and maintain the mandatory OML Quality policy and QMS procedures as well as such additional documentation as may be required.

Manage and maintain compliance with regulatory requirements relating to OML medical devices. Primarily the EC Medical Devices Directive (93/42/EEC + 2007 revisions) as well

as Canadian (CMDCAS) and US FDA guidance. Compliance is demonstrated by compilation of a Technical File (= Device Master Record) plus policy and procedures incorporated into the QMS. This includes reporting of incidents, recalls etc to appropriate Competent Authorities (MHRA) and national bodies.

Prepare and submit applications and supporting documentation to all the overseas national regulatory authorities or contracted third parties where OML is active in order to register the legal distribution of OML products in these territories. Maintain these registrations by necessary communications, fees etc. in consultation with OML CEO. Currently compliance is in place for EU (France/Benelux, Germany, Italy, Turkey, Romania), South Africa, New Zealand and Canada with applications lodged with USA and pending for Australia.

Manage the OML IT infrastructure accounting for present and future needs through personal and externally contracted support. Sales, finance, operations and clinic management rely on the IT provision as well as email and other shared data facilities. (2x server Windows Server based network on 1 Gigabit wired network)

Participate in OML Senior Management Team representing the above duties in order to determine, plan and deliver OML strategic objectives.

-- x --

Changes in JD between A4C (Oct 2004) and CSE reconfiguration 2010

Dr. Steven Crook,
Consultant Clinical Scientist & OML Quality, Regulatory and IT Manager

SNHSFT

Core Trust duties and responsibilities are very similar. The requirement for the Trust to comply with various radiation related H&S legislation, guidance and licence conditions is unchanged since 2000. The revised CSE management structure will create an extra layer of line management between the Medical Physics Section and the Directorate.

Radiology has undergone a major change with the introduction of digital imaging. SNHSFT is now a filmless site with a mixture of CR and DR imaging. This technology introduction requires different QA tests to be performed by physicists and radiographers. These are still developing nationally.

Expansion of cardiac Nuclear Medicine led to the appointment of an additional Clinical Scientist (Physicist) to support the service. (Line managed by the post holder). With this addition, support to radiology will be enhanced and lapsed support (specialised measurements & QA) to other areas (e.g. UV therapy) will be reinstated. An equipment bid to provide the necessary instruments has been submitted. This bid is necessary as support from adjacent Medical Physics Depts is no longer provided although an 'old boy' network operates for advice and professional issues.

Support for laser QA and advice has been transferred from the postholder to Dr. Philip Wright who is based within the Wessex specialist laser centre.

Since A4C the postholder has taken on management of the Salisbury DXA scanning service. This is an outpatient facility with a throughput of roughly 1200 patients per annum. Role consists of equipment management for the scanner (QA and organising servicing), technical/scientific advice to medical staff and public plus management of operators (radiology APs) while they are within the Laing Building. Postholder checks the resulting scan reports to make sure the correct computer interpretation has been made. Patient advice not given.

Support in Theatres and Spinal Outpatients for bladder stimulator implants has lapsed. Tentative discussions have taken place regarding support to Urology for a similar technology to be taken up in Salisbury. (Trust)

The Quality Manager role was previously entirely within the Trust. The electrical stimulation aspects are now within Odstock Medical Ltd. Postholder still overseeing the quality management system in Medical Engineering and their ISO9000 registration although day to day activities transferred to Andrea Taylor (Clinical Scientist).