Royal Free London NHS
NHS Foundation Trust

JOB DESCRIPTION

JOB TITLE:	Senior Radiopharmacist / Radiopharmaceutical Scientist
DIVISION:	Clinical Services
SALARY BAND:	AfC Band 8a
RESPONSIBLE TO:	Head of Radiopharmacy
ACCOUNTABLE TO:	Head of Radiopharmacy
CLINICALLY RESPONSIBLE TO:	Lead Clinician in Nuclear Medicine / Chief Pharmacist
HOURS PER WEEK:	37.5
LOCATION:	Nuclear Medicine Department, Radiopharmacy, Ground Floor

JOB SUMMARY:

The Royal Free London NHS Trust is a modern teaching hospital situated in North London near Hampstead Heath. The Nuclear Medicine department, with three gamma cameras and two PET/CT cameras for diagnostic imaging, undertakes many imaging investigations, a specific range of laboratory-based tests and a range of therapy procedures.

The Radiopharmacy is situated within the Nuclear Medicine department, housing four negative pressure isolators and fully equipped QC lab; supplying a range of diagnostic and therapeutic radiopharmaceuticals to the Nuclear Medicine Department and the National Amyloidosis Centre, under a MHRA Manufacturer's Specials Licence.

The Radiopharmacy also holds a MIA(IMP) Licence which allows the unit to manufacture radiopharmaceuticals for clinical trials, to contribute to a range of research activities based on collaboration with other departments of the hospital, the medical school and with other hospitals.

The Radiopharmacy also assist in the procurement of radiopharmaceuticals and providing clinical support.

The post-holder will be a member of the team of pharmacists, scientists and technicians contributing to QA and the Pharmaceutical Quality System, supporting clinical trials and routine production and quality control of all types of radiopharmaceuticals.

JOB PURPOSE

- To support maintaining, monitoring and developing quality assurance and general day to day supervision and aspects of the provision and delivery of the Radiopharmacy service.

- To maintain the Pharmaceutical Quality System of the Radiopharmacy service which is a requirement of EU Good Manufacturing Practice and the Manufacturer's "Specials" Licence issued by the Medicines and Healthcare products Regulatory Agency (MHRA).

- To act as an authorised releasing officer for radiopharmaceuticals.

- To carry out production and quality control duties for diagnostic and therapeutic radiopharmaceuticals.

- To develop, implement and follow measures and systems for maintaining compliance with quality assurance, relevant legislation, guidelines, protocols and SOPs.

- To be designated by the Trust as an operator under the Ionising Radiation (Medical Exposure) Regulations *(IR(ME)R)* and as a Classified Worker under the Ionising Radiations Regulations (IRR).

Duties

This post is subject to the terms and conditions of employment of The Royal Free London NHS Trust.

The postholder is required to work to extremely high standards of accuracy and safety, involving significant personal responsibility for product quality. The post holder will be expected to work independently and undertake complex tasks and operate complex equipment**,** in accordance with QA, GMP compliance, local rules and standard operating procedures.

Date of the JD review: **14/02/24**

MAIN DUTIES AND RESPONSIBILITIES

Royal Free World Class Values

The post holder will offer World Class Care to service users, staff, colleagues, clients and patients alike so that everyone at the Royal Free can feel:

- Welcome all of the time
- Confident because we are clearly communicating
- Respected and cared for
- Reassured that they are always in safe hands

Detailed duties will alter and develop in response to changing service needs but currently include the following:

1. **CLINICAL/TECHNICAL RESPONSIBILITIES**

- Jointly with other members of the senior scientific Radiopharmacy team, be involved in development, validation and delivery of radiopharmacy services and complex radiolabelling service.
- Participate in the aseptic production of both diagnostic and therapeutic radioactive medicinal products for clinical use, including investigational medicinal products for clinical trials, operating within the terms of Standard Operating Procedures. This requires drawing up radioactive doses (from heavy lead pots) through heavy and bulky lead protected syringes, many calculations and following complex and precise steps.
- Undertake a co-ordinator and checking role during routine aseptic production; two staff members must be involved to check and to double-check the correctness of calculations and measurements; ensuring also that all radiopharmaceuticals are in accordance with the specifications.
- Undertake a range of quality control tests on radiopharmaceuticals, using unsealed sources of radioactivity, operating within the terms of Standard Operating Procedures, to ensure compliance with pharmacopoeial standards; ensuring these results are recorded accurately and that any failures are reported.
- Process and calculate results from such QC tests, and enter the confirmed results on to records for verification.
- Responsible for verifying results and reports prepared by technical staff.
- Responsible for safely operating expensive and complex equipment, including, among others, isolators, gamma counters, dose calibrators, radiochromatogram scanners, HPLC, pH meters, filter integrity testers, Pharmtracer synthesis module and Geiger counters.
- Expected to act as an authorised releasing officer, performing under delegated authority, the final release of radioactive and non-radioactive medicinal products for clinical use.
- Carry out routine scheduled checks, readings and quality control tests for areas and equipment that the post holder is responsible for.

- Responsible for ensuring that all equipment and facilities for which they are responsible are maintained in such a way as to ensure correct functioning and specification.
- Review and trend analysis of microbial and physical environmental monitoring and reported results.
- Comply with relevant statutory requirements, as defined in The Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Medicines and Healthcare products Regulatory Agency).
- Jointly with the senior scientific Radiopharmacy team, maintain the comprehensive Radiopharmacy Pharmaceutical Quality Management System, including the writing and review of Standard Operating Procedures, validation of premises and processes, change control, accurate recording and investigation of Unusual Events, their CAPA, risk assessments, OOS, OOT.
- Pack and dispatch radioactive materials to internal or external (national and international) sites in such a way as to comply with the requirements for lawful transport of radioactive materials by road / air.
- Liaise with radiopharmaceutical manufacturers to ensure a continuing provision of suitable radiopharmaceutical products to ensure continuity of service provision.
- Provide support to all members of the Radiopharmacy team when required, allowing for flexibility in working patterns to promote efficiency in the Radiopharmacy.
- Operation of the computer systems; including responsibility for ensuring that all entries follow data integrity and data governance.
- Responsible for ensuring that records of procedures, which the post holder has performed or supervised, are properly completed and maintained on the paper or computer based system. The post holder will ensure that the correct data is entered at the relevant times and that, in any event, all records are up to date by the end of the working day.
- Liaise with professional and technical staff and other service users where necessary including when there are service problems and delays.
- Assist in the development, review, writing and implementation of new and existing procedures and their upkeep.
- Constantly working in a radiation area. The staff member must therefore be continually aware of and exercise radiation safety and security practices.
- Monitor and record radioactive contamination and waste.
- Deal with radiation contamination and undertaking containment and decontamination procedures where necessary and accumulate / dispose of radioactive and pharmaceutical waste in accordance with Standard Operating Procedures, in keeping with regulations of the EA including calculations of radioactivity levels.
- Report incidents involving health and safety, radiation protection, quality assurance.
- Responsible for trend analysis of results, evaluating and reporting out of specification results for continual quality improvement.

- Carry out, when required, other duties appropriate to the grade that have been discussed with the post holder.

2. RESPONSIBILITY FOR PATIENTS

- Professionally and legally take responsibility for providing a high standard of clinical care and supporting other staff within Radiopharmacy, Nuclear Medicine and other service users, to do likewise.
- Act as the role of 'operator' as defined in The Ionising Radiation (Medical Exposure) Regulations. These regulations also require the post holder to follow a continuing professional training and development programmes.
- Be familiar with the range of clinical applications of the full range of available radiopharmaceuticals and adjunct medicines used.
- Provide advice for service users on radiopharmaceuticals relating to safe and effective use including storage, formulation, drug interactions and potential adverse reactions and unusual biodistribution.
- Provide assistance on the supply of all medicines including radiopharmaceuticals used in Nuclear Medicine including procurement, receipt, delivery, formulary updates, Drugs & Therapeutics applications and writing drug evaluations.
- Demonstrate respect for patient dignity and empathy with patients and their escorts whilst working in the Nuclear Medicine clinical area, especially in difficult or emotional circumstances, using both verbal and non-verbal communication skills.
- Follow Trust infection control policies.

3. EDUCATIONAL RESPONSIBILITIES

- Contribute to the training and induction support in the technical and theoretical aspects of Radiopharmacy work, to the relevant level for trainee clinical scientists, pre-registration pharmacists, student technicians / technologists, specialist registrars, MSc students. Also to host and teach visitors observing technical work.
- Responsible for the ongoing development and maintenance of the Radiopharmacy training program, as part of the overall Pharmaceutical Quality Management System.
- Provide comprehensive training to new Radiopharmacy / Nuclear Medicine staff and on-going training to existing staff,
- Undertake formalised assessments for postgraduate students and document the findings in accordance with each academic institution's requirements.
- Responsible for providing teaching on aspects of Radiopharmacy for teaching courses.
- Help foster a culture of life-long learning and development, including provision of vocational training within Radiopharmacy.
- Offer support, advice and motivation to junior staff.

- Undertake continuing professional development (CPD) as required to maintain status as an operator, as defined in the Ionising Radiation (Medical Exposure) Regulations 2000.
- Undertake such continuing professional development (CPD) as required to maintain state registration and maintain own competency to practice and personal development.
- Keep abreast with relevant legislation and guidance updates.
- Keep abreast of the latest scientific and technical developments and their applications in medical and associated fields, and attend seminars and courses as part of personal development and to further the work of the Department.
- Attend relevant courses, conferences or scientific meetings, as agreed by the head of radiopharmacy and ensure relevant information is brought back to the department.
- Have an agreed personal development plan and follow to meet set knowledge and competencies, and identify further training needs as required with the Head of Radiopharmacy.
- Maintain an up to date knowledge of the Trust-wide issues and procedures including dealing with sharps, needle stick injuries, infection control and clinical waste disposal.

4. RESPONSIBILITY FOR LEADING AND MANAGING

- Ensure the monthly self-inspection of the Radiopharmacy Pharmaceutical Quality systems (PQS) and service is completed, and an action plan for addressing the findings is prepared as well as delivering some of the requirements of the related action plans.
- Collate key performance indicators, as required for the PQS management.
- Attend regular meetings of Radiopharmacy and Nuclear Medicine, and present relevant findings from the monthly PQS meeting.
- Be present during inspections of the Radiopharmacy by QA, Inspectors from the MHRA, EA and the HSE.
- Ensure a safe and secure environment for staff and patients. In particular support safeguards against theft of radioactive material and ensure staff fully comply with these safeguards
- Plan and prioritise own workload continually throughout the day, occasionally under conditions of high pressure and in consideration with the delivery of the radiopharmacy service.
- Jointly, with senior Radiopharmacy Technicians to plan and co-ordinate service delivery requirements to ensure that all requested items can made with the available radioactivity and all necessary tasks are performed on schedule, to set deadlines. This may include organising, rescheduling and prioritising work and supervising the deployment of technical staff as well as deploying contingency plans
- Jointly with the other senior radiopharmaceutical scientist / pharmacist, act as deputy to the Head of Radiopharmacy, to cover for some of the

routine duties normally performed, apart from in those areas where the post-holder is not legally permitted to do so.

- Contribute to providing information and advice on department workload and services, to enhance the service to Nuclear medicine, and other departments.
- Act to resolve any problems that arise during manufacture, the operation of the facility and any equipment, operating within the terms of Standard Operating Procedures.
- Act as a lead on the delivery of new services.
- Ensure prompt and effective communication systems within the Radiopharmacy team are in place.
- Liase with Estates department, external contractors with regards to PPM and repair work of equipment, HVAC and facilities.
- Carry out, when required, other duties appropriate to the grade that have been discussed with the post holder, that might reasonably be required.
- Report any instances of sickness in a timely manner and as dictated by Trust and departmental policy for self and junior staff.
- Participate in the recruitment process for Radiopharmacy staff, jointly with other senior staff.
- Actively participate in the Trusts appraisal process as an appraisee.
- Actively participate in the Trusts appraisal process as an appraiser for junior staff, including setting clear objectives and personal development plan.
- Identify training and development needs of staff in line with departmental and Trust objectives.
- Ensure performance issues are dealt with in an appropriate and timely manner and follow Trust disciplinary or poor performance procedures where formal action is necessary.
- Handle and respond to complaints received.

5. RESPONSIBILITY FOR POLICY AND SERVICE DEVELOPMENT

- All duties must be carried out in accordance with the Health and Safety at Work Act, The Medicines Act 1968, The Radioactive Substances act 1993. The Ionising radiation Regulations, The Ionising Radiation (Medical exposures) Regulation and The Data Protection Act 1984 and any other relevant Guidance notes and Departmental Local Rules
- Be designated as an ***IR(ME)R operator*** by the Trust in respect to Radiopharmacy technical duties and know the legal implications involved.
- Be designated as a Classified Worker by the Trust under the Ionising Radiations Regulations (IRR). This will include participation in personal monitoring for radioactive contamination.
- Be designated as a Radiation Protection Supervisor (RPS) (following suitable training), if required, to be responsible, under the guidance of the Radiation Protection Adviser, for the radiological safety of radiopharmacy staff.

- Work in accordance with Local Rules, relevant legislation, codes of practice and regulations relating to the use of radioactive material and, in general, to observe safe procedures and good practice in all aspects of patient investigations and radiation work.
- Work in accordance with SOPs, following GMP, QA and GCP.
- Review current practice and propose changes where appropriate where benefit to users, other healthcare professionals and patients may result, to contribute to the development of the radiopharmacy service.
- Respond positively and manage the introduction and implementation of change affecting the nature, direction and delivery of radiopharmacy services, such that the required outcomes are achieved in an efficient, timely and cost effective manner with minimum disruption to service delivery.
- To review and comment on continuing appropriateness of SOPs.
- Adapt, and quickly respond to changes in service or departmental need.

6. RESPONSIBILITY FOR FINANCIAL AND PHYSICAL RESOURCES

- Participate in the co-ordination of ordering, ordering and receipt radiopharmaceuticals and other items from external suppliers using the Trust ordering system, if required.
- Maintain records of receipt, storage and disposal of items, operating within the terms of Standard Operating Procedures, to fulfil Environmental Agency regulations and GMP.
- Source suitable and new items / manufacturers as required.
- Advise on purchasing of equipment, radiopharmaceuticals and other items.
- Responsible for the care and safe handling of equipment and accessories in the area of work.
- Contribute to finding cost savings and time efficiencies.
- Ensure that equipment faults are recorded appropriately and reported.
- Make suitable provision for the service in the event of equipment failure.
- Make suitable arrangements to fix equipment failures.
- Ensure records surrounding the above events are maintained.
- Prepare costings and invoices for radiopharmacy services.
- Liase on contracts and waivers for services as required.
- Produce and issue service level agreements and technical agreements to external customers and contractor services.

7. RESPONSIBILITY FOR INFORMATION RESOURCES

- Ensure that data entries and print outs are presented for checking purposes in a timely and accurate manner, ensuring data integrity.
- Support the cascading of information through the team, department and customers.
- Monitor and report deficits in the data governance and data integrity of the Radiology Information System (RIS) and the Pharmaceutical Quality System (PQS), in use in the department.

- Undertake evaluation and validation of software used in Radiopharmacy.

8. RESPONSIBILITY FOR RESEARCH AND DEVELOPMENT

- Jointly with other members of the senior scientific Radiopharmacy team, be involved in a range of clinical trial related activities, including reviewing protocols, assessing feasibility, assisting in the set-up and GCP administration of clinical trials, and involvement in site initiation, meetings, audits and monitoring visits.
- Receive materials and conduct accountability according to GCP and the protocol for a range of clinical trials.
- Undertake research and development activities as appropriate, in support of the overall research program agreed between the Head of Radiopharmacy and service users.
- Present results of work at scientific meetings (national and international).
- Proactively undertake service development, to deliver service and efficiency improvements where possible.
- Supervise technicians, trainees and students in undertaking research projects.
- Participate in the Nuclear Medicine Academy programmes of the department as required.
- Prepare and present short presentations or audit presentations for the biannual audit day.
- Actively participate in aspects of the department's audit programme.
- Evaluate methods and equipment and their technical application and suitability.

GENERAL RESPONSIBILITIES

Infection Control

Infection control is everyone's responsibility. All staff, both clinical and non clinical, are required to adhere to the Trust's Infection Prevention and Control policies and procedures and the Health Act (2006) Code of Practice for the prevention and control healthcare associated infections and make every effort to maintain high standards of infection control at all times thereby reducing the risk of Healthcare Associated infections.

It is the duty of every member of staff to take personal responsibility for the prevention and control of infection, as laid down in the Trust's polices and procedures which reflect the statutory requirements of the Hygiene Code.

- To work in close collaboration with the Infection Control Team.
- To ensure that monitoring of clinical practice is undertaken at the agreed frequency.
- To ensure that the ward environments are cleaned and maintained to the highest standards; ensuring that shortfalls are rectified, or escalate as necessary.
- To ensure that all relevant monitoring data and issues are provided to the Directorate's Governance structures.

- To ensure that all staff are released to attend infection control-related educational sessions and staff with specialist roles, e.g. link practitioners, are released to undertake their duties.

Health and Safety at Work
The post holder is required to:

- Take reasonable care for the health and safety of himself/herself and other persons who may be affected by their actions or omissions at work.
- Co-operate with the employer in ensuring that all statutory and other requirements are complied with.

Confidentiality & Data Protection
The post holder has a responsibility to comply with the Data Protection Act 1998 and maintain confidentiality of staff, patients and Trust business.
If you are required to process information, you should do so in a fair and lawful way, ensuring accuracy is maintained. You should hold information only for the specific registered purpose and not use or disclose it in any way incompatible with such a purpose.
You should disclose information only to authorised persons or organisations as instructed. Breaches of confidentiality in relation to information will result in disciplinary action, which may include dismissal. Employees are expected to comply with all Trust policies and procedures and to work in accordance of the Data Protection Act 1998. For those posts where there is management or supervision of other staff it is the responsibility of that employee to ensure that their staff receive appropriate training (e.g. HISS induction, organising refresher sessions for staff when necessary.)

Conflict of Interest
The Trust is responsible for ensuring that the services for patients in its care meet the highest standards. Equally, it is responsible for ensuring that staff do not abuse their official position, to gain or benefit themselves, their family or friends.

Equality and Diversity
The Trust values equality and diversity in employment and in the services we provide. It is committed to promoting equality and diversity in employment and will keep under review our policies and procedures to ensure that the job related needs of all staff working in the Trust are recognised. The Trust aims to ensure that all job applicants, employees or clients are treated fairly and valued equally regardless of sex, marital status, domestic circumstances, age, race, colour, disablement, ethnic or national origin, social background or employment status, sexual orientation, religion, beliefs, HIV status, gender reassignment, political affiliation or trade union membership. Selection for training and development and promotion will be on the basis of the individual's ability to meet the requirements for the job.
You are responsible for ensuring that the Trust's policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and services.

Vulnerable Groups

- To carry out responsibilities in such a way as to minimise risk of harm to children, young people and vulnerable adults and to promote their welfare in accordance with the Children Act 2004, Working Together to Safeguard Children (2006) and No Secrets guidance (DH 2000).
- To demonstrate an understanding of and adhere to the trust's child protection policies.

Smoke Free

The Trust implements a Smoke Free policy that applies to all staff. Staff are not allowed to smoke while wearing a recognisable Trust uniform or visible trust identification badge, and not allowed to smoke anywhere on hospital grounds. Staff are not allowed to take additional breaks in order to smoke. They may smoke during designated breaks but only out of uniform and off site. Staff contravening this policy may be subject to disciplinary procedures**.**

Standards of dress

All staff are expected to abide by the Trust's guidance on standards of dress.

This job description outlines the current main responsibilities of the post. However, the duties of the post may change and develop over time and may therefore, be amended in consultation with the post holder.