

## JOB DESCRIPTION

### 1. JOB IDENTIFICATION

Job Title:	Specialist Quality Assurance Technician, Radiopharmacy
Responsible to:	Senior Quality Assurance Radiopharmacist
Department(s):	Radiopharmacy
Directorate:	Pharmacy
Operating Division:	Corporate
Job Reference:	181956
No of Job Holders:	1
Last Update (insert date):	27 Oct 2023

### 2. JOB PURPOSE

Perform Quality Control (QC), Quality Assurance (QA) and Production duties associated with manufacturing sterile radioactive injections (radiopharmaceuticals) to nine hospitals, across three Health Boards (NHS Lothian, NHS Fife, NHS Borders).

Assist in the maintenance of the Pharmaceutical Quality System of the Radiopharmacy. This will include the investigation of deviations, performing risk assessments, conducting validation work, carrying out change control and performing other QA tasks required to maintain the Manufacturer's "Specials" Licence issued by the Medicines and Healthcare products Regulatory Agency (MHRA).

Responsible for the safety of Radiopharmacy staff working with ionising radiation, as Deputy Radiation Protection Supervisor, to ensure radiation protection standards and staff radiation doses comply with the Ionising Radiation Regulations 2017 (IRR17).

### 3. DIMENSIONS

#### **Scope**

The Radiopharmacy provides radiopharmaceuticals for approximately 11,000 patients per year in the Nuclear Medicine departments and theatres of nine hospitals across Lothian, Fife and the Borders, and is responsible for the purchase, receipt and delivery of all radioactive materials used in NHS Lothian, including research conducted at the University of Edinburgh, comprising a budget of £750,000 per year. The Radiopharmacy operates under an MHRA "Manufacturer's Specials" (MS) licence and is inspected regularly by the MHRA against the very high standards of the European Union Good Manufacturing Practice (EU GMP) regulations.

#### **Staff Responsibilities**

Responsible for the day to day safety of staff handling ionising radiation, by providing radiation protection education and monitoring of behaviours in practice while working in Radiation Controlled Areas. Perform IRR17 risk assessments to ensure staff radiation doses are as low as reasonably

practicable (ALARP), as dictated by IRR17 regulations.

Monitor and review the performance of technical and support staff in the Radiopharmacy, including work allocation and rota planning of quality assurance and revalidation work. Review personal development and training plans for technical staff, regarding QA and radiation protection work, and participate in recruitment and selection as required.

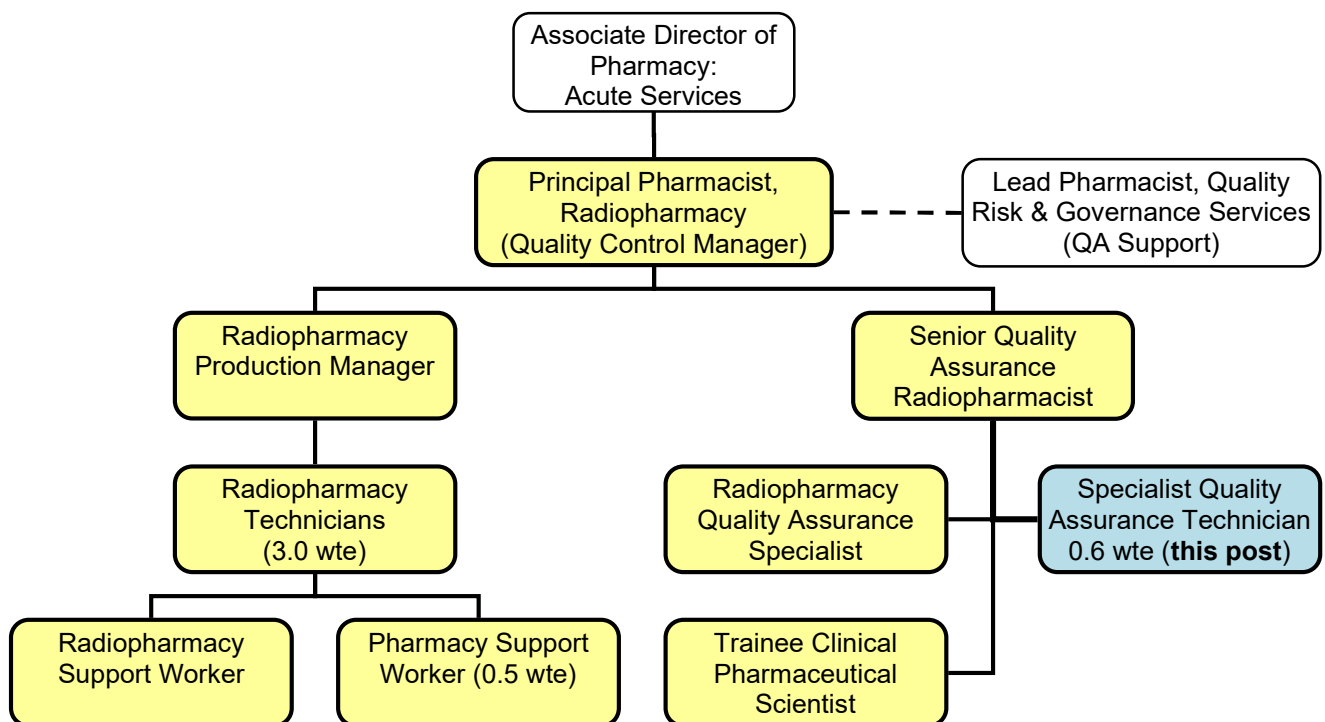
The post-holder is employed by NHS Lothian and there may be a requirement to work flexibly across NHS Lothian Pharmacy sites to meet service demands.

Participation in the public holiday and weekend working rota of the Pharmacy Department at the Royal Infirmary of Edinburgh.

### Financial Responsibilities

Authorised signatory against the Radiopharmacy's two budgets for the purchase of radiopharmaceuticals and supplies to the value of £5,000.

## 4. ORGANISATIONAL POSITION



## 5. ROLE OF DEPARTMENT

The aim of the Pharmacy Service is to assure quality of patient care in the provision of treatment with medicines. To this end, the objectives are:

- (i) To provide pharmaceutical care to individual patients by meeting their particular needs whilst maximising efficiency in the use of resources.
- (ii) To provide medicines through systems of quality control which ensure safe, effective and economic use.

The NHS Lothian Acute Pharmacy Service achieves these objectives through the provision of the Pharmaceutical Quality System, which is certified by the British Standards Institution (BSI) and regularly inspected by the Medicine and Healthcare Products Regulatory Agency (MHRA) in both Radiopharmacy and Clinical Trials.

The Department of Pharmacy provides services to primary and secondary centres throughout Lothian.

Services include dispensing, aseptic, clinical, radiopharmacy, procurement and distribution, medicines information, medicines management and quality assurance. These services are currently delivered across 4 Health and Social Care Partnerships and 7 hospital sites: the Western General Hospital (WGH), the Royal Infirmary of Edinburgh (RIE), the Royal Hospital for Children and Young People (RHCYP), St John's Hospital (SJH), Royal Edinburgh Hospital (REH), East Lothian Community Hospital (ELCH) and Liberton Hospital (LIB).

The Department of Pharmacy dispenses over 543,000 prescription items, 686,000 pre labelled packs, 9300 total parenteral nutrition bags 34,000 intravenous additives, 38,000 cytotoxic products, 900 intrathecal products, 11,000 radiopharmaceutical products and processes 55,000 Controlled Drug orders per annum. The department has approximately 327WTE staff. The combined drug budget for NHS Lothian hospitals is £96.6million per annum. The budget is not held by the pharmacy service but expenditure against this is monitored and reported on to senior management. The average monthly stockholding across the pharmacy services is £7.15 million with month stock value issues of £6.2million. Approximately 152,000 lines are ordered and 995,000 lines are supplied per annum. 492 locations across Lothian are supplied on a weekly basis.

## **6. KEY RESULT AREAS**

### **(i) Main duties and responsibilities**

1. Assist the Senior QA Radiopharmacist in ensuring the Radiopharmacy operates according to the terms of its Manufacturer's "Specials" Licence, as defined by the EU Guidance on Good Manufacturing Practice (EU GMP). This will be achieved by: assisting in the development and review of standard operating procedures; training of new and existing staff in quality control and quality assurance; monitoring quality control results of products, equipment and facilities; raising and investigating deviations from out of specification results; writing change control reports, performing risk assessments, and ensuring the Pharmaceutical Quality System (PQS) is kept up to date with current GMP standards and the recommendations from auditors and inspectors.
2. Perform the final release of sterile, radioactive unlicensed medicines manufactured under the Radiopharmacy's Manufacturer's Specials licence for administration to patients undergoing diagnostic nuclear medicine scans or molecular radiotherapy.
3. Direct responsibility for the day to day supervision of radiation safety in the Radiopharmacy, ensuring compliance with IRR17 by observing Radiopharmacy staff at work and assessing the appropriateness of procedures and equipment used for radiation safety. Plan and deliver training sessions for all Radiopharmacy staff on radiation protection and supervise staff undertaking duties required to provide evidence of competence for structured training plans, as required by IRR17 and EU GMP.
4. Maintain accurate records of Radiopharmacy staff radiation exposure levels and report instances where radiation dose limit alert levels are exceeded, to the Radiation Protection Supervisor (RPS) or directly to the NHS Lothian Radiation Protection Advisor (RPA) in the absence of the RPS.
5. Perform radiation risk assessments, in line with the standards required by the Health and Safety Executive and the Office of Nuclear Regulation, including the calculation of potential radiation exposure to staff from performing new and existing procedures, for final approval by the RPS and RPA.
6. Monitor the Radiopharmacy's compliance with the Scottish Environmental Protection Agency (SEPA) registration, by ensuring the correct procedures for storage and disposal of radioactive materials and radioactive waste is adhered to at all times.
7. Perform final product quality control tests on manufactured sterile injections in the laboratory, including high-performance liquid chromatography, thin-layer chromatography, bubble-point and endotoxin tests.
8. Analyse and check the results of final product quality control tests on manufactured sterile injections performed by other staff and independently make decisions on the suitability of the QC test results to release the products for administration to patients.

9. Perform the required validation assessments and quality control checks to validate new medicinal products, new procedures or new equipment, to ensure they meet with EU GMP standards for sterile medicines manufacture and radiation safety, before being used in the Radiopharmacy.
10. Review of critical tests and trend analysis of results, including environmental monitoring and instrument calibration to ensure the Radiopharmacy facility and equipment is performing within EU GMP specifications.
11. Raise, investigate, and review deviation reports, arising from out of specification results from quality control checks of products, equipment and environmental monitoring, including writing corrective and preventative action (CAPA) reports. Respond to product quality complaints from customers, both verbally at the time of initial reporting and in writing, in the form of an official report of the outcome of deviation investigations.
12. Monitor recent legislative and regulatory changes in EU GMP and radiation protection (IRR17), and contribute to the update of Radiopharmacy procedures and Radiopharmacy staff training in accordance with this.
13. Participate in Radiopharmacy production sessions, including the sterile manufacture of technetium-99m and gallium-68 radiopharmaceuticals, under IRR17 and EU GMP regulations. This requires validation and maintenance of competency in aseptic manufacture, material transfer and procedures for entering and working in clean room environments to minimise the risk of microbial contamination to sterile products.
14. Responsible for ordering radiopharmaceuticals and supplies to the total value of £5,000 as an Authorised Signatory for both the Radiopharmacy Trading Account and the Radiopharmacy Gallium Budget.
15. Plan and organise revalidation of all Radiopharmacy staff for performing sterile manufacturing duties with unsealed sources of ionising radiation to ensure that all staff members remain validated to perform all duties required to undertake their roles in the manufacture of sterile medicines under EU GMP and IRR17.
16. Participate in internal and external audit of the Radiopharmacy service including regular inspection by the MHRA, the Office of Nuclear Radiation (ONR) and SEPA. Contribute to the development and completion of action plans to correct non-conformances identified by internal and external audits.
17. Administrator or super-user of the Radiopharmacy Laboratory Information Management System (LIMS), with involvement in the design and adaptation of the LIMS and the development of new procedures and functionality. Train new and existing staff in the use of the LIMS and perform the validation and revalidation of the LIMS and the QC equipment it connects to.
18. Competently use, conduct quality control tests and perform first-line diagnosis of faults in all equipment and critical instruments used in Radiopharmacy. Organise the revalidation of existing Radiopharmacy equipment and instrumentation, including the performance of QC tests or the review of results of tests undertaken by external providers.
19. Support NHS Lothian's values of quality, teamwork, care and compassion, dignity and respect, and openness, honesty, and responsibility through the application of appropriate behaviours and attitudes.

#### **7a. EQUIPMENT AND MACHINERY**

The types of equipment used in Radiopharmacy, for which the post-holder must be proficient in the use of, includes:

- Radionuclide generators: where unsealed radioisotopes are produced for use in manufacture
- Radionuclide calibrators: which measure the amount of radiation in patient doses
- Laboratory QC instruments, such as the high performance liquid chromatograph (HPLC); the thin-layer radiochromatogram scanner and the gamma-ray spectrometer for the identification and quantification of radioisotopes and to measure the radiochemical purity of products manufactured to determine their suitability for patient use
- Radiation monitors (Geiger counters and scintillation detectors) for the detection of radioactive

contamination in the working area

- Radiation dose-rate monitors for the measurement of radiation doses to staff while performing certain tasks and for assessing radiation risk
- Clean air devices, such as the Grade A laminar air-flow safety cabinets and the PET isolator, as well as the QC laboratory fume cupboard

An understanding of the operation of the air handling plant that supplies sterile air to the aseptic suite is also required.

**Note:** New equipment may be introduced as the organisation and technology develops, with the post-holder leading the validation of its use in production and the training of Radiopharmacy staff in its use.

## 7b. SYSTEMS

The following are examples of systems which the post-holder will have administrator or super-user rights for, and will provide training to other staff on their use:

- The Radiopharmacy Laboratory Information Management System (LIMS)
- Radiopharmacy database to record workload and prepare worksheets, labels, delivery notes and dispatch documentation
- Radiopharmacy Laboratory QC Software (LabLogic TLC & HPLC)

The following are examples of systems used by all Radiopharmacy staff to undertake the duties involved in manufacturing radiopharmaceuticals for patient administration:

- Software systems: Pharmacy stock control and dispensing system (CMM)
- Procurement system for ordering materials, medicines and equipment (PECOS)
- Pharmacy management information reporting system
- Microsoft Office for word processing, spreadsheets, e-mail, internet access
- Datix incident management system
- Turas personal development and review system
- The Radiopharmacy Pharmaceutical Quality System
- The Pharmacy Quality System (BS EN ISO 9001:2015)
- Environmental Monitoring Systems

**Note:** New systems may be introduced as the organisation and technology develops, with the post-holder leading the validation of their use in production and the training of Radiopharmacy staff in its use.

## 8. ASSIGNMENT AND REVIEW OF WORK

Meets and consults with the QA Specialist and the Senior QA Radiopharmacist on a regular basis to review the Quality Assurance service provision and determine future developments.

Review of performance is carried out by the Senior QA Radiopharmacist in accordance with the principles of personal development and the Knowledge & Skills Framework.

Agree objectives with the Senior QA Radiopharmacist, with three monthly review and annual appraisal.

## 9. DECISIONS AND JUDGEMENTS

Perform final release of radiopharmaceuticals or other unlicensed "Specials" for injection into patients by performing or analysing the in-process and final product quality control checks, or reject batches in the event of deviation from the product specification.

Independently make decisions regarding the safety of Radiopharmacy staff from the hazards of ionising radiation, including in emergency situations, in the role of Deputy Radiation Protection Supervisor.

Provide critical information to the Senior QA Radiopharmacist and QC Manager to effectively manage

all risks to the patient attributable to the sterile manufacture of unlicensed medicinal products and the use of ionising radiation for diagnostic tests and therapy. This may involve critical appraisal of quality control test data to inform decisions on product quality and facility compliance with GMP standards.

Provide recommendations to the Senior Quality Assurance Radiopharmacist following the installation qualification testing of new equipment, instrumentation and digital software systems that are required to meet EU GMP standards for use in the manufacture and quality control testing of sterile medicinal products.

Take appropriate action when results of monitoring or testing are outside specification.

Plan and organise own workload and the workload associated with the Radiopharmacy Quality Management System. Plan workload of others to ensure all revalidation work is undertaken on schedule.

Review standard of work for new, or rotational staff working in the Radiopharmacy and sign-off on their competence to perform GMP tasks or procedures involving the use of ionising radiation.

Act independently within appropriate guidance and consult line manager when necessary.

#### **10. MOST CHALLENGING / DIFFICULT PARTS OF THE JOB**

Decision making involved in the release of unlicensed radioactive medicinal products for injection into patients, with the limited amount of QC data available at the time of release.

As Deputy Radiation Protection Supervisor (RPS) for the Radiopharmacy, working with the RPS to ensure radiation safety procedures are correctly followed by all Radiopharmacy staff working with ionising radiation, and that radiation exposure to all staff in the department is kept below statutory limits, set by IRR17 and enforced by the inspectorate of the Health and Safety Executive.

Continuing to meet the increasing quality standards of EU Good Manufacturing Practice and the Medicines and Healthcare products Regulatory Agency (MHRA) Guidance for Specials Manufacturers, as enforced by the MHRA Inspectorate.

Working effectively as a senior technician as part of the Radiopharmacy team to lead, promote and develop the service within limited resources.

Be available to the inspectorate of the MHRA for matters relating to the quality of manufactured unlicensed medicinal products ("Specials"), and to auditors of compliance with the Ionising Radiation Regulations 2017, in the knowledge that they have the power to withdraw licensing, if not satisfied, which would result in the cessation of the Nuclear Medicine service to nine hospitals across Lothian, the Borders and Fife

#### **11. COMMUNICATIONS AND RELATIONSHIPS**

The communication of results from QC tests will be typically on a one-to-one basis, with either: analysts that have performed the test; the QC Manager (Principal Pharmacist) or Senior QA Radiopharmacist; or the patient's supervising physician/ consultant to determine the validity or significance of results from complex analytical tests that are used to make decisions on whether a product is suitable for administration to patients. This communication will be complex and occasionally contentious where it challenges others' clinical or technical judgement, when deciding to accept or reject a manufactured batch of products.

Provide advice to superintendent radiographers, clinical scientists and medical physics technicians about the quality of radiopharmaceuticals.

Communicate with product suppliers and resolve resulting issues concerning the quality of raw materials and licensed, externally manufactured radiopharmaceuticals.

Communicate with Quality Risk and Governance staff and Microbiology concerning the microbiological monitoring results of the aseptic suite and aseptic processes.

Respond directly to questioning by the Health and Safety Executive Inspector, or Senior Medical Physics Experts, during radiation protection audits of Radiopharmacy's compliance with IRR17.

Respond directly to questioning by the MHRA Inspectorate, during a GMP inspection.

Respond to product quality complaints from customers, both verbally at the time of initial reporting and in writing, in the form of an official report of the outcome of investigations.

Provide both one to one and group education sessions to Radiopharmacy staff regarding radiation protection while working with unsealed radiation sources, including providing assurance to individuals that have concerns about working with ionising radiation.

Demonstrate duties and techniques to less experienced members of staff.

Communicate with nursing staff, radiographers and other practitioners from Radiology departments regarding the use of medicines.

Communicate effectively in a manner in keeping with the professional operation of the Department.

## 12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

Physical:	<ul style="list-style-type: none"><li>• A high degree of manual dexterity is required, involving frequent manipulation of liquid radioactive materials using needles, syringes and small vials, which requires great care to avoid radioactive contamination and rapid working to avoid radiation exposure.</li><li>• Aseptic manipulation skills are essential and will be regularly validated.</li><li>• Regular heavy lifting of lead-shielded equipment for radiation protection. Daily lifting of lead pots weighing 7kg and twice weekly lifting of radionuclide generator, which weighs 18kg. Trolleys are provided for lateral movement between rooms, but no lifting equipment is available.</li><li>• Standard keyboard skills are required</li><li>• Periods of standing for more than two hours while undertaking quality control checks and final release of manufactured products.</li></ul>
Mental:	<ul style="list-style-type: none"><li>• Apply high levels of concentration, precision and accuracy during aseptic manipulation of precise volumes of radioactive liquid</li><li>• High levels of concentration, precision and accuracy when performing quality control checks on medicines in the laboratory</li><li>• High level of concentration when performing final release of radiopharmaceuticals</li><li>• Will be required to perform high-concentration tasks above under strict time pressures, due to the very limited shelf-life of the radioactive medicines manufactured.</li></ul>
Emotional:	<ul style="list-style-type: none"><li>• Provide reassurance to staff that are concerned about working daily with ionising radiation.</li><li>• Investigate and deal with complaints from customers or patients and deal with product quality issues with potentially serious consequences.</li></ul>
Environmental:	<ul style="list-style-type: none"><li>• Daily exposure to ionising radiation.</li><li>• Wearing full-body restrictive clean-room and protective clothing for working in an aseptic environment, with higher air pressure and loud background noise.</li></ul>

### 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

The post-holder should be a qualified Radiopharmacy Technician, Pharmacy Technician, Nuclear Medicine Technologist, Radiographer or Healthcare Science Practitioner registered on the appropriate accredited register for their profession.

#### **Radiopharmacy Technicians:**

- A degree in a physical, biological or other suitable science (physics, chemistry)
- Completion of the necessary accredited post-qualification, competency-based training, to become registered on the Health and Care Professionals Council (HCPC) register or the Register of Clinical Technologists (RCT)
- Registered as a technologist or healthcare science practitioner on the HCPC or RCT registers.
- Post qualification experience as a Radiopharmacy technician, with sufficient experience in an MHRA licensed Radiopharmacy, to be designated to perform final release of manufactured specials, according to the MHRA's Guidance for Specials Manufacturers (see below for details)
- Certificate in Radiation Protection Supervisor (RPS) training, (short course conducted by organisation's Radiation Protection Advisor) sufficient to meet the requirements to be an RPS under the Ionising Radiation Regulations 2017.

#### **Pharmacy Technicians:**

- National Certificate in Pharmaceutical Sciences
- Registered on the General Pharmaceutical Council (GPhC) register as a pharmacy technician
- Designated checking technician qualification in either Dispensary, Aseptic Services or Radiopharmacy
- Post qualification experience as a hospital pharmacy technician, in the pharmaceutical industry, or in an MHRA licensed manufacturing facility, with sufficient relevant GMP experience to be designated to perform final release of manufactured specials, according to the MHRA's Guidance for Specials Manufacturers (see below for details)
- Experience in Radiopharmacy which includes the preparation of sterile radiopharmaceuticals and the performance of quality control checks under the supervision of a radiopharmacist, or under a Manufacturer's Specials licence
- Certificate in Radiation Protection Supervisor (RPS) training, (short course conducted by organisation's Radiation Protection Advisor) sufficient to meet the requirements to be an RPS under the Ionising Radiation Regulations 2017.

#### **Technologists, Radiographers and Healthcare Science Practitioners:**

- A degree in a physical, biological or other suitable science (physics, chemistry, radiography)
- Completion of the necessary post-qualification, competency-based training, to become registered on the Health and Care Professionals Council (HCPC) register or the Register of Clinical Technologists (RCT)
- Registered as a technologist or healthcare science practitioner on the HCPC or RCT registers.
- Post qualification experience as a technologist or healthcare science practitioner in the pharmaceutical industry, or in a GMP facility to be designated to perform final release of manufactured specials, according to the MHRA's Guidance for Specials Manufacturers (see below for details)
- Certificate in Radiation Protection Supervisor (RPS) training, (short course conducted by organisation's Radiation Protection Advisor) sufficient to meet the requirements to be an RPS under the Ionising Radiation Regulations 2017.

#### **Skills and Experience:**

In order to perform final release of sterile medicinal products under a Manufacturer's Specials Licence, the MHRA Guidance for Specials Manufacturers stipulates that individuals performing final release must have "*a recognised qualification in a pharmacy or related subject*" and have "*at least two years post-qualification relevant GMP experience.*"

The post-holder must meet the requirements in qualifications, knowledge and experience stated in the MHRA Guidance for Specials Manufacturers to perform final release of radiopharmaceuticals manufactured by the Radiopharmacy.

Sufficient experience of working with ionising radiation to be able to effectively perform the duties of the Deputy Radiation Protection Supervisor.

#### **14. JOB DESCRIPTION AGREEMENT**

A separate job description will need to be signed off by each jobholder to whom the job description applies.

Job Holder's Signature:

Date:

Head of Department Signature:

Date: