Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Principal Radiochemist (Radiopharmaceuticals Development and Manufacture)
Cluster / Business Unit / Division	Nuclear Science & Technology
Section or Unit:	Biosciences / Radiochemistry
Classification:	Band 7
Job Family:	Research
Position Description Number:	PD-2414
Work Contract Type:	Science / Research
STEMM/NON-STEMM:	STEMM
STEMM CATEGORY:	Research & Sciences

POSITION PURPOSE

The primary objective of the Principal Radiochemist (Radiopharmaceuticals Development and Manufacture) is to lead the development and manufacture of high-quality radiopharmaceuticals. The position leads and undertakes capability development programs to enable and improve radiochemistry manufacturing capabilities to support the translation of radiopharmaceutical technologies into high-quality products. The position holder provides subject-matter expertise to develop and execute early-stage radiopharmaceuticals, including the development of radio-conjugation and radiolabelling technologies, using alpha-emitting and OPAL produced radioisotopes. The position holder uses expertise and experience to build national and international partnerships and collaborations and utilises external and internal networks across the nodes of the National Imaging Facility (NIF), NST and Nuclear Medicine businesses that lead to the delivery of high impact outcomes, contributing to national science and research priorities and ANSTO's strategic imperatives.

ORGANISATIONAL ENVIRONMENT

ANSTO leverages great science to deliver big outcomes. We partner with scientists and engineers and apply new technologies to provide real-world benefits. Our work improves human health, saves lives, builds our industries, and protects the environment. ANSTO is the home of Australia's most significant landmark and national infrastructure for research. Thousands of scientists from industry and academia benefit from gaining access to state-of-the-art instruments every year.

Nuclear Science & Technology (NST) incorporates ANSTO's research, innovation, landmark research infrastructure and associated platforms and capabilities. NST conducts research and development in relation to nuclear science and technology and connects people, transfers knowledge, and provides nuclear-based products and services for the benefit of Australia.

NST Research and Technology Groups include platforms containing scientific infrastructure and research capabilities. Platforms include a range of scientific assets, infrastructure, capability development and delivery for multi-decadal, multi-disciplinary, multi-user platforms for a collaborative user community and for internal research and development endeavours.

The Biosciences platform is organised into three groups – Radiochemistry, Irradiations, and Biology & Preclinical Imaging. The platform partners with pharmaceutical, biomedical, and medical devices companies to bring new products and methods to market. It collaborates with the NST Human Health research theme to develop greater understanding of disease states, diagnosis, and treatment, assists in optimising ANSTO Nuclear Business production methods, and develops new and improved methods of deploying landmark infrastructure and nuclear methods for the benefit of partners, collaborators, and customers.

The Radiochemistry group provides a wide range of capabilities to enable the radiochemistry research and development teams to deliver radiopharmaceuticals, radioisotopes, advanced manufacturing methods and

radioisotope separations. The Radiopharmaceuticals team is focused on the research, development, and the manufacture of new radiopharmaceuticals, working on discovery research through to product development and radiopharmaceutical provision to support preclinical and clinical evaluation. The team develops new radiochemistry technologies/techniques, applies established radiochemistry technologies to new targets, and optimises the production and formulation of radiopharmaceutical products to deliver world class outcomes. Including manufacturing processes and methodologies to optimise the production of radiopharmaceuticals and radioisotopes. Using automated radiosynthesis modules following GMP and GLP principles, to provide radiopharmaceuticals and radioisotopes manufacture procedures, technologies, and products at production scale. They achieve this by leveraging extensive radiochemistry capabilities for manual and automated radiosynthesis, accessing a broad range of reactor radioisotopes and radiolabelling techniques. The team delivers high value by working closely with the Radioisotopes team, Nuclear Medicine Development team, and the Preclinical Imaging and Biology group. The Radiopharmaceuticals team collaborates with partners from the academia, (radio)pharmaceutical industry, and hospitals.

The Alpha Radiopharmaceuticals Facility forms part of the national NIF network of nodes. The facility is located at Lucas Heights and incorporates a dedicated alpha radiochemistry development capability in the MFB facility as part of the Radiochemistry group. The alpha development facility contains a glovebox, automation modules and QC equipment to produce alpha-emitting radiopharmaceuticals for pre-clinical studies initiated by ANSTO researchers, partners, collaborators, and customers.

ACCOUNTABILITIES & RESPONSIBILITIES

- Provide research leadership in the development and provision of new and early-stage therapeutic radiopharmaceuticals using alpha, and OPAL produced radioisotopes. Including the development of radio-conjugation and radiolabelling technologies.
- Lead the development of radiopharmaceutical manufacturing capabilities for the translation of new radiopharmaceutical technologies into high-quality products. Including the development of high-quality and reproducible radiochemistry automation and radio-analytical measurement methods.
- Lead and develop advanced manufacture techniques to deliver new or improved capabilities, apply then at scale radiopharmaceutical production, to optimise radiochemistry yield, reliability, purity, and stability.
- Lead and conduct routine radiopharmaceutical production and propose, evaluate, validate, and execute new and improved manufacture methods for routine supply of radiopharmaceuticals and radioisotopes to user communities.
- Fulfil the role of Facility Fellow of the National Imaging Facility (NIF), meeting specified performance indicators in the areas of research, facility utilisation, networking, engagement, communication, reporting, and national coordination.
- Lead and assist in the preparation of scientific reports, publish papers, reports, patents, and abstracts, presenting results in national and international forums.
- Makes significant contribution towards the management of radiopharmaceutical laboratories and equipment through an asset management framework and assist with the capital development program to ensure the availability and utilisation of capabilities, meeting operational safety, security, sustainability and compliance requirements within applicable standards, legislation, and regulations.
- Lead and assist in the development and maintenance of quality, safety, and compliance programs. Write SRA, SWMES, work instructions and procedures for equipment usage and for safe experimental practice, validation records and protocols. Ensure equipment is used properly, safely and in accordance with ANSTO policies and procedures.
- Develop and maintain extensive national and international networks to represent ANSTO and NIF, identify and secure collaborative research opportunities with strategic partners, including international government radiochemical research and manufacturing laboratories, universities, and industry.
- Undertake additional duties as required and during period of leave of other staff.

Decision Making

- The ANSTO values, organisational corporate plan, integrated business planning process, the NST strategic plan and the Biosciences business plan provide the context for the position.
- Determine key work priorities and methods for the Radiopharmaceuticals team within the context of agreed work plans and in consultation with the Principal Radiochemist (Radiopharmaceuticals Manager) and other radiochemistry capability managers.
- The position is fully accountable for the accuracy, integrity and quality of advice provided, ensuring that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure or in the absence of complete information or expert advice.
- The position works within a framework of legislation, policies, professional standards, and resource parameters.
- The levels of authority delegated to this position are those approved and issued by the Chief Executive Officer. All delegations will be in line with the ANSTO Delegation Manual AS-1682 (as amended or replaced).

Key Challenges

- Building effective and productive networks across ANSTO and externally.
- Keeping abreast of recent advances in radiopharmaceutical development and manufacture, laboratory management, quality systems and radiation safety, ensuring continual improvement, implementation of best practice and maximising the user experience.
- Balancing operational and strategic demands in a highly complex, heavily regulated, tightly constrained, and dynamic environment to ensure successful delivery of agreed objectives.
- Understanding and balancing the different expectations from a variety of users, collaborators, and partner communities, particularly ANSTO nuclear medicine businesses and the external nuclear medicine community.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Principal Radiochemist (Radiopharmaceuticals Manager)	• Receive broad guidance and direction. • Receive performance requirements consistent with the business plan and objectives. • Report on compliance of the instrumentation. • Receive guidance on the alignment and direction of radiopharmaceutical development and manufacturing projects. • Provide advice on operational and capital budgetary requirements. • Recommend and gain approval for facility modifications, enhancements, improvements, and process/procedure changes or improvements. • Escalate issues and propose solutions. • Provide regular updates on key tasks, issues, and priorities. • Provide expert, authoritative and evidence-based advice.
Radiochemistry Team Members	• Deliver to the business plan. • Lead team members and work collaboratively to contribute to the delivery of high impact outputs. • Provide expert scientific advice, analysis, and leadership. • Influence and shape group decision making processes, planning, and goals. • Collaborate and share accountability. • Identify and negotiate solutions to conflicting demands on resources.

Internal researchers, facility users and capability providers	• Collaborate and share knowledge. • Provide expert advice, analysis, guidance, and support. • Monitor trends, progress against agreed project plans, and develop strategies to ensure project delivery. • Provide user supervision and ensure safety, regulatory and quality compliance. • Negotiate access to OPAL irradiation facilities and associated support services. • Gather intelligence on trends within the field of scientific discipline.
External	
ANSTO Nuclear Medicine and NST subject matter experts	• Collaborate and share knowledge. • Provide expert advice, analysis, and leadership.
Nuclear medicine community, universities, industry, national and international research organisations, post graduate and undergraduate students	• Provide expert advice and analysis • Build effective and productive networks • Identify opportunities for productive engagement and facilitate access • Ensure safety and regulatory compliance • Provide training and supervision while using ANSTO's facility
National Imaging Facility	• Receive guidance on the measures of success applicable to the Alpha Radiopharmaceuticals Facility • Provide regular updates to the ANSTO NIF node Director. • Provide expert input to the Australian Molecular Imaging and Radiochemistry Network, particularly on opportunities to expand the national capability for alpha particles and the development of a national radioisotopes laboratory for beta particles.

POSITION DIMENSIONS

Staff Data

Reporting Line	Principal Radiochemist (Radiopharmaceuticals Manager)
Direct Reports	Nil
Indirect Reports	x2 Radiochemist

Financial Data (2022/2023)	
Revenue / Grants	N/A
Operating Budget	N/A
Staffing Budget	N/A
Capital Budget	N/A
Assets	N/A

Special / Physical Requirements

Location:	Lucas Heights Working in different areas of designated site/campus as needed
Travel:	Operational needs may require temporary and/or periodic assignments at collaborative partner facilities within Australia or training assignments both nationally and internationally.

Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) Laboratory facility physical requirements (manual handling, standing for extended periods, operating machinery & equipment) Wearing personal protective equipment for the handling of hazardous and/or radioactive materials
Radiation areas:	Will be required to work in radiation areas and undertake duties in an area where radioactive materials are handled under tightly regulated and controlled safety conditions Perform duties with and in an area where hazardous chemicals or materials are handled under tightly controlled safety conditions Perform duties in an area where radioactive materials are handled under tightly controlled safety conditions
Hours:	Willingness to work extended and varied hours based on operational requirements
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements

Workplace Health & Safety	
Specific role/s as specified in AG-2362 of the ANSTO WHS Management System	All Workers Other specialised roles identified within the guideline a position holder may be allocated to in the course of their duties

ORGANISATIONAL CHART

Refer to published Organisational Chart.

KNOWLEDGE, SKILLS, AND EXPERIENCE

1. PhD in radiochemistry, inorganic, organic or medicinal chemistry or pharmaceutical sciences.
2. Extensive knowledge and experience with the manufacture of radiopharmaceuticals, their development and radioanalytical measurement.
3. Significant knowledge and experience in the development of radiopharmaceuticals, radio-conjugation and or radiolabelling methods.
4. Extensive experience and knowledge in a senior role, demonstrated technical leadership, the supervision of staff and students, including coaching and mentoring skills, provision of constructive feedback on performance, as well as giving advice and guidance on ways of developing skills, knowledge, and experience.
5. Good project management experience, including the co-ordination of the work of other staff, effective deployment of resources, ability to manage multiple parallel tasks, management of priorities and organisational skills.
6. Demonstrated ability to lead teams to deploy radiopharmaceuticals or radioisotopes capabilities.
7. Proven experience ensuring own work and the work of others complies with quality, safety, standards, regulatory and statutory requirements, ideally gained through working within a highly regulated manufacturing environment.
8. Demonstrated high level interpersonal, communication and negotiation skills with the capacity to influence key decision-makers.
9. Demonstrated experience to develop and maintain productive working relationships and networks with a wide variety of staff, commercial and academic partners, and regulators.
10. Proven research leadership and publication track record in radioisotope and/or radiopharmaceutical manufacturing method development.

VERIFICATION

This section verifies that the line manager and appropriate senior manager/executive confirm that this is a true and accurate reflection of the position.

Line Manager		**Delegated Authority**	
Name:	TBA	Name:	John Bennett
Title:	Principal Radiochemist (Radiopharmaceuticals Manager)	Title:	Leader, Biosciences
Signature:		Signature:	
Date:		Date:	

Appendix 1

ANSTO Job Families
Accounting & Finance
Administration
Communications & Marketing
Compliance & Regulation
Engineering and Technical
Human Resources
ICT & Digital Solutions
Information & Knowledge Management
Legal
Manufacturing
Monitoring & Audit
Operations
Organisational Leadership
Project & Program
Research
Science
Security & Intelligence
Senior Executive
Service Delivery
Strategic Policy
Trades & Labour