



## Position Description

POSITION TITLE:	MITRU Lead Engineer
LOCATION:	SAHMRI, North Terrace
REPORTS TO:	Operations Manager, MITRU
DEPARTMENT:	Molecular Imaging and Therapy Research Unit (MITRU)

### PURPOSE AND SCOPE OF THE POSITION

The MITRU Lead Engineer will work with a multidisciplinary team of scientists to manufacture radiopharmaceuticals under current Good Manufacturing Practice (cGMP) for routine clinical use and in clinical trials. The individual will provide specialist input into the commissioning, licencing and accreditation process and ongoing management, maintenance and operation of MITRU equipment and engineered systems.

The role requires specialist expertise to effectively operate and service the cyclotron in radioisotope production and to provide technical advice for existing equipment and new projects. Further, the role requires a radiation licence to operate and maintain the cyclotron and to work with the RSO to ensure the hazards associated are minimised.

Reporting to the Operations Manager, the MITRU Lead Engineer will be responsible for ensuring the equipment in MITRU is maintained, calibrated, and repaired according to schedule or as required (i.e., unplanned shutdown). The position will also work closely with SAHMRI Engineering and both internal and external service providers. The role may also interact with a range of external stakeholders including nuclear medicine departments, medical representatives, researchers, cyclotron manufacturers, suppliers, contractors, research industry networks and regulatory bodies.

The MITRU Lead Engineer is also considered a MITRU Engineer and retains all MITRU Engineer responsibilities. The MITRU Lead Engineer has additional responsibilities and is expected to lead the MITRU Engineering team (when established).

### KEY RESPONSIBILITIES

The specific duties include:

- Plan and manage preventative and breakdown maintenance of MITRU equipment and services (including the building and services) in collaboration with SAHMRI staff and contractors to minimise downtime.
- Manage equipment commissioning/decommissioning and provide specialist input into accreditation process in conjunction with the equipment supplier when required.
- Lead and document investigations into equipment-related issues as part of deviations and identifying suitable corrective and preventative actions (CAPAs).
- Manage and implement qualifications and/or validations for new/existing equipment.
- Contribute/provide specialist input to ensure that MITRU systems meets ISO, ARPANSA, EPA, TGA and any other regulatory requirements.
- Manage the technical operation of the cyclotron, including fault analysis, to ensure that the cyclotron runs at optimal performance and supports production carried out at the SAHMRI facility.
- Assess and control equipment performance against budgets and take appropriate corrective action where necessary.



- Ensure the operations' functions are completed in a timely, cost-efficient manner to meet client's specified commitments.
- Manage administration and back-up of computerised manufacturing systems.
- Train staff in aspects for the cyclotron and MITRU equipment associated with quality, operations, radiation safety, GMP and GLP to ensure all work is carried out to established Standard Operating Procedures (SOPs), within safe operating limits and complies with all regulations.
- Manage and update Work Instructions (WIs), SOPs and other documentation related to equipment.
- Propose and assist in acquiring new equipment and managing tenders, offers, quotes and ensure due diligence regarding infrastructure and associated installation issues.
- Ensure the Equipment Register, Work Orders and validation activities are updated and maintained.
- Monitor the performance of external equipment associated contractors.
- Recommend efficient solutions to improve process and workflows within the MITRU and MITRU equipment.
- Assist with research and development projects as required.
- Participate in the internal audit program.
- Keep up to date with legislative and regulative changes as they impact the cyclotron and MITRU equipment operations.
- Keep updated with strategic trainings that will help achieve role requirements.
- Participate in special projects to continuously improve processes, tools, systems and organisation.
- Take reasonable care to protect own health, safety and welfare at work and avoid affecting the health and safety of any other person at work.
- Participate in the implementation of the Institute's Work, Health and Safety Management System and related laws, regulations and guidelines.
- Ensure that duties are performed in keeping with the principles outlined in SAHMRI's Vision, Mission and Values and the **Code of Conduct Policy**.

## SPECIAL REQUIREMENTS

- Some out of business hours is required to ensure impact on commercial work is minimised and will be organised with the MITRU Director, Operations Manager or designee.
- Irregular interstate travel may be required.
- Must be available on an on-call basis for troubleshooting if there is unexpected equipment failure.
- This position requires a pre-employment medical examination to determine suitability for the physical requirements of the role.
- Must participate in regular health assessments.



## Person Specification

### QUALIFICATIONS

- Degree or higher qualification in Engineering, Physics or other health and science related discipline
- Specialised training in the use and maintenance of cyclotrons and radiochemistry systems is preferred

### KEY BEHAVIOURAL COMPETENCIES

The MITRU Lead Engineer must:

- Work closely with the QA and AP to keep quality systems suitable in all areas related to the release, manufacture and supply of goods accredited
- Work cooperatively in a team environment with competing interests for equipment
- Communicate effectively and be able to train team members in the use of equipment
- Be able to troubleshoot problems with equipment and relay issues to contractors in the production and QC Laboratory if they arise
- Use sound judgement and have a strong commitment to quality
- Drive continuous improvement through innovation and development of process efficiency
- Have well-developed analytical and problem-solving skills and attention to detail
- Be innovative, resourceful and creative
- Be results driven with demonstrated ability to work in a dynamic environment and to set and meet deadlines to realise organisational objectives
- Possess good interpersonal skills and have a demonstrated capacity to work cooperatively in a team environment
- Commitment to providing internal and external client service of a high standard

### EXPERIENCE, KNOWLEDGE AND SKILLS

- Experience in target preparation and maintenance and troubleshooting of cyclotron and radiochemistry systems is preferred
- Practical knowledge of radiation protection related to cyclotron operation is preferred
- Practical knowledge of radioactivity
- Knowledge of ISO Standards, GMP, GLP, EPA, ARPANSA and TGA requirements
- Experience and knowledge in the maintenance of plant, equipment and systems
- Experience and knowledge in the qualification and validation of GMP equipment and systems.
- High level of attention to detail; methodical with excellent record keeping skills
- Ability to prioritise own workload and meet deadlines
- Ability to work independently, seeking support when necessary to complete the task
- Ability to work effectively in a team, manage positive working relationships and establish rapport
- Proficiency in the use of Microsoft Office Suite of products



- High level of written and verbal communication skills
- Capability to supervise and give guidance as required to staff working in the Facility
- Support SAHMRI's commitment to reconciliation and acknowledge the importance of working in partnership with Aboriginal and Torres Strait Islander People
- Able to demonstrate the following SAHMRI Values and Culture:
  - **Excellence** – Bold, Driven, Dynamic
  - **Innovation** – Persistent and Focused
  - **Courage** – Collaborative and Enabling
  - **Integrity** – Embrace Diversity, Demand Equity
  - **Teamwork** – Friendly, Fast, Flexible, Fun

## LICENCES

- EPA license to handle radioactive substances and use ionising radiation apparatus (may be obtained during employee's probationary period as per 'special conditions').

## APPROVED BY

**Name:**

**Position:**

**Signature:**

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Date     /     /

**Incumbent:**

**Signature:**

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Date     /     /