Nuclear Medicine Services

Government of South Australia
SA Health

Module Overview

Please note: This module must be read in conjunction with the Fundamentals of the Framework (including glossary and acronym list).

Nuclear medicine is the medical specialty that uses unsealed radioactive sources (radiopharmaceuticals) to diagnose and treat adults and children with a variety of disease processes (including neurological conditions, cardiovascular disease and cancer). Radiopharmaceuticals are radiolabelled tracers targeting specific organs, tissues or disease processes; they are administered to the patient via injection, inhalation or ingestion. The radiopharmaceuticals used in diagnostic nuclear medicine emit gamma rays that can be detected externally by specialised imaging systems such as gamma cameras and positron emission tomography (PET) scanners. These imaging systems may also be combined with computed tomography (CT) or magnetic resonance imaging (MRI) scans creating hybrid systems known, for example, as single photon emission tomography / computed tomography (SPECT/CT) or positron emission tomography / computed tomography (PET/CT). Diagnostic nuclear medicine can include non-imaging procedures where radiopharmaceuticals are measured in body samples (e.g. blood or urine). Radiopharmaceuticals used in nuclear medicine therapy emit alpha and beta radiation in quantities designed to destroy target tissues.

Nuclear medicine is often collocated with other diagnostic imaging services. It is described separately in the CSCF as it has distinctive clinical and technical support requirements, staffing, and training and accreditation requirements.

Radioisotope laboratories, which manufacture radiopharmaceuticals for use at other institutions or for commercial sale, may also come under the Commonwealth jurisdiction of the Therapeutic Goods Act 1989 (and amendments) and Therapeutic Goods Regulations, through the need to conform to the *Australian Code of Good Manufacturing Practice for Medicinal Products.*[1] Separate regulations may apply to the manufacture of radiopharmaceuticals for PET.

The Australian and New Zealand Society of Nuclear Medicine (ANZSNM) is the peak body representing nuclear medicine in Australia. In addition, Australasian Association of Nuclear Medicine Specialists (AANMS) operates as the peak body representing nuclear medicine specialists such as physicians and radiologists.

The regulation of radiopharmaceutical manufacture and reconstitution is currently under review. Where possible, services should strive to meet the Guidelines for Good Radiopharmacy Practice.[2]

Service Requirements

In addition to the requirements outlined in the Fundamentals of the Framework, specific service requirements include:

- adequate radiation safety measures must be observed and the service must comply with the South Australia Radiation Protection and Control Act 1982 and South Australia Radiation Protection and Control (Ionising Radiation) Regulations 2015.
- compliance with SA Health policy directives and guidelines that are referenced at:
  - SA Health Policy Directives
  - SA Health Policy Guidelines
  - SA Health Clinical Directives and Guidelines
- certificates of compliance are required for any radiation apparatus, some radiation sources, and the rooms in which they are housed.
- gamma cameras and other equipment and devices must be technically adequate and sufficiently maintained to perform any procedure, with staff adequately trained and competent in their use as outlined in the Minimum Quality Control Requirements for Nuclear Medicine Equipment.[3]

- administration of radiopharmaceuticals, along with all other drugs, must comply with prevailing legislation and/or regulation.
- nuclear medicine departments offering registrar training must be accredited as a training site by the Joint Specialist Advisory Committee of the Royal Australasian College of Physicians (RACP) and Royal Australian and New Zealand College of Radiologists (RANZCR) following a site visit by the Training Site Accreditation Committee (TSAC) of the AANMS.
- clinical training of Medical undergraduate and Nuclear Medicine Technologist undergraduates will be performed as part of accredited university courses.
- *Safety and Performance Guidelines for Exercise Testing and the Safety and Performance Guidelines for Pharmacologic Stress Testing in Conjunction with Clinical Cardiac Imaging Procedures*[4] must be followed when using pharmacologic agents for cardiac stress testing in conjunction with clinical imaging procedures.
- equipment required in the provision of nuclear medicine services is not identified in this document; where a range of equipment is recommended, the health facility is expected to provide the type most suitable for its needs.
- Sites performing PET have to meet and be accredited for PET scanning and training by the ANZSNM and recognised by the HIC.
- nuclear medicine practices are encouraged to participate in the Practice Accreditation Programme.[5]
- anaesthesia may be used for nuclear medicine studies, especially for young children.
- any use of anaesthetics must comply with the Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites or Other Anaesthetising Locations.[6]
- provide relevant clinical indicator data to satisfy accreditation and other statutory reporting obligations.

Workforce Requirements

The CSCF does not prescribe staffing ratios, absolute skill mix, or clerical and/or administration workforce requirements for a team providing a service, as these are best determined locally and in accordance with relevant industrial instruments. Where minimum standards, guidelines or benchmarks are available, the requirements outlined in this module should be considered as a guide only. All staffing requirements should be read in conjunction with the *Health Care Act 2008*, Awards and relevant Enterprise Agreements including, but not limited to:

- SA Health Salaried Medical Officers Enterprise Agreement 2013
- SA Health Visiting Medical Specialists Enterprise Agreement 2012
- SA Health Clinical Academics Enterprise Agreement 2014
- Nursing/Midwifery (South Australian Public Sector) Enterprise Agreement 2013
- SA Ambulance Service Enterprise Agreement 2011
- SA Public Sector Wages Parity Enterprise Agreement Salaried 2014

In addition to the requirements outlined in the Fundamentals of the Framework, specific workforce requirements include:

- nuclear medicine must be practised only by a Nuclear Medicine Physician supported by Nuclear Medical Technologists, Physicists or Radiochemists.
- All Nuclear Medicine specialists are to be recognised as such by JSAC (The joint Specialist Advisory Committee) of the RACP and RANZCR and credentialed for scope of practice within SA Health. They are to be registered as nuclear medicine specialists with AHPRA
- Nuclear Medicine technologists must be registered with AHPRA and maintain CPD activity.
- medical staff, technologists and scientific staff must hold a valid Radiation Use Licence with the SA environment protection authority.
- medical staff, technologists and scientific staff must hold Radiation Safety Use Licence with SA Health.
- nuclear medicine physicists accredited by the ACPSEM.
- ACPSEM accreditation is a requirement for physicists supervising a PET practice.

> registered nurses employed in a nuclear medicine department may, but are not limited to:
  - case managing patients receiving high-dose therapy treatments
  - supporting patients requiring electrocardiography (ECG) and vital sign monitoring
  - collecting blood samples and assisting with processing and shipping of samples
  - inserting urinary catheters for PET scan patients (adult and children).

Specific Risk Considerations

In addition to risk management outlined in the Fundamentals of the Framework, specific risk considerations for medical imaging services include:

> Maintenance of compliance with the Commonwealth Department of Health Capital Sensitivity for Diagnostic Imaging Equipment.

Nuclear Medicine Services	Level 4	Level 5	Level 6
Service description	> provides basic diagnostic nuclear medicine studies. > will have established formal processes with public or suitably licensed private health facilities. > examples of procedures performed are bone and lung scans as well as some interventional studies requiring presence of nuclear medicine specialist, such as stress myocardial perfusion and captopril renal	> has an after-hours service. > access to commercial or in-house supply of radiopharmaceuticals during working hours. > offers treatment with radiopharmaceuticals (e.g. radioiodine for hyperthyroidism), which may be provided independently of nuclear medicine department.	> includes highest level transfer / referral centre. > radioisotope laboratory available on-site and staffed by radiochemists. > PET services may also be available. > provides therapeutic administration of high dose radiopharmaceuticals including treatment for inpatients (e.g. radioiodine for thyroid cancer patients, radioiodinated meta-iodobenzylguanidine [MIBG] scintiscan for metastatic neuroendocrine tumours). > Note: if service does not include GMP-compliant laboratory, this may limit provision of some types of therapy and research.

Nuclear Medicine Services	Level 4	Level 5	Level 6
Service requirements	As per module overview, plus: > resuscitation and monitoring facilities available. > preparation or reconstitution of radiopharmaceuticals occurs with clear and appropriate documentation including details of source of supply, preparation date, and batch number. > staff qualified and experienced in monitoring, maintenance and use of equipment. > quality control programs established. > access to cardiac stress testing and stress testing equipment. > bone mineral densitometry may be available. > radiopharmaceuticals may be reconstituted in a Good Manufacturing Practice (GMP) compliant laboratory or purchased from such a laboratory. > radiopharmaceuticals may be reconstituted on-site; if so, current Guidelines for Good Radiopharmacy Practice (AANMS) apply. > may have facility for in vivo and/or in vitro tracer studies.	As per Level 4, plus: > treatment with radiopharmaceuticals available. > an after-hours call service. > documented processes in place for access to production or reconstitution of radiopharmaceuticals. > may offer PET studies.	As per Level 5, plus: > appropriate inpatient isolation facilities for therapeutic administration of high-dose radiopharmaceuticals. > dedicated radiopharmaceutical laboratory on-site and staffed by radiopharmacist / radiochemist with capacity to produce radiopharmaceuticals, extending beyond reconstitution of commercial products (where these activities occur, there must be compliance with relevant State and National regulatory standards and formal GMP certification may be required in cases of commercial manufacture). > 24-hour on-call service.
Workforce requirements	**As per module overview, plus:** Medical > registered and licensed nuclear medicine specialist present during radiopharmaceutical administration; only variation to this is where formal exemptions granted by Health Insurance Commission for remote and rural areas. > full-time supervision during procedures by nuclear physician or radiologist with nuclear medicine qualification. Nursing > staffing levels in accordance with the relevant industrial instruments. > suitably qualified and experienced registered nurse responsible for patient's airway and providing care where patient requires sedation. Allied health > registered nuclear medicine technologist. Other > qualified expert who meets Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) requirements appointed as designated radiation safety officer.[8]	**As per Level 4, plus:** Medical > nuclear medicine specialist accessible for consultation 24 hour/s. Nursing > staffing levels in accordance with the relevant industrial instruments. > access to suitably qualified and experienced registered nurse appropriate to service being provided. > nursing staff on-site during hours of operation of department and accessible after hours, as required. Allied health > access—during business hours—to radiochemist / radiopharmacist. > medical physicist accessible on-site during business hours where PET procedures performed. Other > access to technical support staff (biomedical engineering scientific officers), as required.	**As per Level 5, plus:** Allied health > access to medical physicist. > full-time radiopharmacist / radiochemist accessible if radiopharmaceuticals manufactured in-house.
Specific risk considerations	Nil	Nil	Nil

Support services requirements for nuclear medical services	Level 4		Level 5		Level 6	
	On-site	Accessible	On-site	Accessible	On-site	Accessible
Medical imaging	4		4		4	
Pathology		3		3		3
Pharmacy	4		4		5	

Legislation, regulations and legislative standards	Non-mandatory standards, guidelines, benchmarks, policies and frameworks
Refer to the Fundamentals of the Framework for details.	Refer to the Fundamentals of the Framework for details.

Reference List:

1. Therapeutic Goods Administration. Australian Code of Good Manufacturing Practice for Medicinal Products. Canberra: Australian Government Department of Health and Ageing; 2002. www.tga.gov.au/docs/html/gmpcodau.htm
2. Australian and New Zealand Society of Nuclear Medicine. Guidelines for Good Radiopharmacy Practice. ANZSNM; 2001. www.anzsnm.org.au/
3. Australian and New Zealand Society of Nuclear Medicine. Minimum Quality Control Requirements for Nuclear Medicine Equipment. ANZSNM; 1999. www.anzsnm.org.au/
4. Cardiac Society of Australia and New Zealand. Safety and Performance Guidelines for Clinical Exercise Stress Testing. CSANZ; 2008. www.csanz.edu.au/
5. Australasian Association of Nuclear Medicine Specialists. Practice Accreditation Programme: Standards for Accreditation of Nuclear Medicine Practices. AANMS; 2005. www.aanms.org.au
6. Australian and New Zealand College of Anaesthetists. Technical Standard T1: Recommendations of Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations. ANZCA; 2008. www.anzca.edu.au/resources/professional-documents/
7. Australian and New Zealand Society of Nuclear Medicine. Supervised Practice Program (SPP) Accreditation Board of the ANZSNM. www.anzsnm.org.au/
8. Australian Radiation Protection and Nuclear Safety Agency. Code of Practice: Radiation Protection in the Medical Applications of Ionizing Radiation. Canberra: Australian Government; 2008. www.arpansa.gov.au/pubs/rps/rps14.pdf

For more information

SA Health
Telephone: 08 8226 6891
www.sahealth.sa.gov.au

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Interpreter

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