

# Nuclear Medicine Services

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## Module overview

Please note: This module must be read in conjunction with the Fundamentals of the Framework (including the 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 that target 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 may also include non-imaging procedures where radiopharmaceuticals are measured in body samples (e.g. blood or urine). The radiopharmaceuticals used in nuclear medicine therapy emit alpha and beta radiation in quantities designed to destroy the target tissues.

Nuclear medicine is often collocated with other diagnostic imaging services. However, it is described separately in the Framework 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*.<sup>1</sup> 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, the Australian and New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM) 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.<sup>2</sup>

## 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 *Queensland Radiation Safety Act 1999* and Queensland Radiation Safety Regulation 1999
- 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*<sup>3</sup>
- administration of radiopharmaceuticals, along with all other drugs, must comply with the Health (Drugs and Poisons) Regulation 1996
- nuclear medicine departments that offer registrar training must be accredited as a training site by the Joint Specialist Advisory Committee of the Royal Australasian College of Physicians (RACP) and the Royal Australian and New Zealand College of Radiologists (RANZCR) following a site visit by the Training Site Accreditation Committee (TSAC) of the ANZAPNM
- the *Safety and Performance Guidelines for Exercise Testing* and the *Safety and Performance Guidelines for Pharmacologic Stress Testing in Conjunction with Clinical Cardiac Imaging Procedures*<sup>4</sup> 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
- nuclear medicine practices are encouraged to participate in the Practice Accreditation Programme<sup>5</sup>
- 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.<sup>6</sup>

## Workforce requirements

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

- nuclear medicine must be practised only by nuclear medicine specialists who are registered with the Medical Board of Australia, assisted by nuclear medicine technologists who are registered by Medical Radiation Technologists Board of Queensland (MRTBQ), and supported by specially trained physicists and radiochemists or radiopharmacists accredited by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)
- medical staff, technologists and scientific staff must hold a Radiation Safety Use Licence with Queensland Health
- nuclear medicine technologists must be registered to work in Queensland by the MRTBQ and accredited by the ANZSNM—if a nuclear medicine department wants to offer technologist training, it must be approved as a suitable place to employ probationary registrants under the Supervised Practice Program<sup>7</sup> (SPP) and accredited as a training site
- 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:
  - case manage patients receiving high-dose therapy treatments
  - study patients requiring electrocardiography (ECG) and vital sign monitoring
  - collect blood samples and assist with the processing and shipping of samples
  - insert urinary catheters for PET scan patients (adult and paediatric).

## Level 4 Nuclear Medicine Service

### Service description

A Level 4 service provides basic diagnostic nuclear medicine studies. The service will have established formal processes with public or suitably licensed private health facilities. Examples of procedures performed at this level are bone and lung scans as well as some interventional studies requiring the presence of a nuclear medicine specialist such as stress myocardial perfusion and captopril renal studies.

### 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 trained and competent in the 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, the current *Guidelines for Good Radiopharmacy Practice* (ANZSNM) apply.

### Workforce requirements

As per module overview, plus:

#### Medical

- a registered and licensed nuclear medicine specialist present during radiopharmaceutical administration; the only variation to this is where formal exemptions have been granted by the Health Insurance Commission for remote and rural areas
- full-time supervision during procedures by nuclear physician or radiologist with nuclear medicine qualification

#### Nursing

- a registered nurse with relevant competency must be responsible for the patient's airway and for providing care where a patient requires sedation
- may have a registered nurse with evidence of ongoing clinical competency and experience appropriate to the service being provided as required by practice guidelines

#### Allied health

- a registered nuclear medicine technologist

## Other

- a qualified expert who meets the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) requirements appointed as a designated radiation safety officer.<sup>8</sup>

## Support service requirements

A Level 4 service requires:

| Service         | On-site | Accessible |
|-----------------|---------|------------|
| medical imaging | 4       |            |
| medication      | 4       |            |
| pathology       |         | 3          |

## Level 5 Nuclear Medicine Service

### Service description

A Level 5 service has an after-hours service. Access to a commercial or in-house supply of radiopharmaceuticals is available during working hours. A Level 5 service will offer treatment with radiopharmaceuticals (e.g. radioiodine for hyperthyroidism), which may be provided independently of the nuclear medicine department.

### Service requirements

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 have the facility for in vivo and/or in vitro tracer studies
- may offer PET studies.

### Workforce requirements

As per Level 4, plus:

#### Medical

- a nuclear medicine specialist is available for consultation 24 hours

#### Nursing

- a registered nurse with evidence of ongoing clinical competency and experience appropriate to the service being provided
- nursing staff on-site during the hours of operation of the department and available after hours, as required

#### Allied health

- as per Level 4 service

#### Other

- access—during business hours—to a radiochemist/radiopharmacist
- registered nuclear medicine technologists
- a medical physicist available on-site during business hours where PET procedures performed
- access to technical support staff (biomedical engineering scientific officers), as required.

**Support service requirements**

A Level 5 service requires:

| Service         | On-site | Accessible |
|-----------------|---------|------------|
| medical imaging | 4       |            |
| medication      | 4       |            |
| pathology       |         | 3          |

## Level 6 Nuclear Medicine Service

### Service description

A Level 6 service includes the highest level transfer/referral centre. A radioisotope laboratory is available on-site and staffed by radiochemists. PET services may also be available. If the service does not include a GMP-compliant laboratory, this may limit the provision of some types of therapy and research. A Level 6 service 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).

### Service requirements

As per Level 5, plus:

- therapeutic administration of high-dose radiopharmaceuticals, including those requiring treatment as inpatients (e.g. radioiodine for thyroid cancer, radioiodinated MIBG scintiscan for metastatic neuroendocrine tumours) with appropriate inpatient isolation facilities
- a dedicated radiopharmaceutical laboratory on-site and staffed by a radiopharmacist/radiochemist with the capacity to produce radiopharmaceuticals, extending beyond the reconstitution of commercial products. Where these activities occur, there must be compliance with relevant State and National regulatory standards. Formal GMP certification may be required in cases of commercial manufacture
- 24-hour on-call service
- highest level transfer/referral centre
- PET studies may be available.

### Workforce requirements

As per Level 5, plus:

#### Medical

- as per Level 5 service

#### Nursing

- as per Level 5 service

#### Allied health

- as per Level 4 service

#### Other

- one or more full-time medical physicists
- a full-time radiopharmacist/radiochemist available if radiopharmaceuticals are manufactured in-house.

## Support service requirements

A Level 6 service requires:

| Service         | On-site | Accessible |
|-----------------|---------|------------|
| medical imaging | 4       |            |
| medication      | 5       |            |
| pathology       |         | 3          |

## Legislation, regulations and legislative standards

Refer to the Fundamentals of the Framework for details.

## Non-legislative standards, guidelines, benchmarks, policies and frameworks

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](http://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/servlet/NM](http://www.anzsnm.org.au/servlet/NM)
3. Australian and New Zealand Society of Nuclear Medicine. Minimum Quality Control Requirements for Nuclear Medicine Equipment. ANZSNM; 1999. [www.anzsnm.org.au/](http://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/](http://www.csanz.edu.au/)
5. Australian and New Zealand Association of Physicians in Nuclear Medicine. Practice Accreditation Programme: Standards for Accreditation of Nuclear Medicine Practices. ANZAPNM; 2005. <http://www.anzapnm.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/](http://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/servlet/NM?page=5&name=Accreditation\\_Home](http://www.anzsnm.org.au/servlet/NM?page=5&name=Accreditation_Home)
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.arpsa.gov.au/pubs/rps/rps14.pdf](http://www.arpsa.gov.au/pubs/rps/rps14.pdf).