AUSTRALASIAN ASSOCIATION of
Nuclear Medicine
Specialists (AANMS)

Australasian Association of Nuclear Medicine Specialists (AANMS) Position Statement on Practice of Theranostics in Australia (Version 1, dated February 2021)

Table of Contents

Acknowledgements

This AANMS Position Statement has been led by the Theranostics Working Group, in collaboration with the relevant stakeholders in the Australian and New Zealand Society of Nuclear Medicine (ANZSNM).

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Executive Summary

Therapeutic options in malignant disease are expanding rapidly with the aim of improving patient outcomes. With the increasing cost of health care, there is a need to ensure the most cost-effective modalities are both available and appropriately implemented as part of the armamentarium of therapies available for patients. Molecular imaging and radionuclide therapy are relatively new options that offers many benefits, including cost and safety, in comparison to those currently available.

Theranostics is a term that has been coined to cover the use of a radiopharmaceutical for both diagnosis and, after demonstrating appropriate levels of concentration of the radiopharmaceutical in tumours, subsequent therapy. This often, though not universally, involves a different isotope bound to the same targeting ligand.

This position statement establishes a consensus on recommendations regarding the care of patients receiving theranostic therapy and to support the provision of safe, high quality, targeted care by qualified professionals in this area. These recommendations include, but not limited to: identifying the optimal workplace and facility requirements; specialist training requirements; patient workflow and MDT requirements.

While a range of theranostic therapies are currently available, there is sufficient commonality among these therapies to allow uniform guidelines to be developed whilst accepting that some specific flexibility will be necessary. Important aspects of theranostics considered in the development of these guidelines include:

- The rapidly evolving scientific and technological advances in the practice of theranostics often see a delay between availability and sufficient clinical evidence to indicate widespread use
- The design of disease, and patient specific, treatment options and delivery methodologies
- The complexity of managing patients with cancer when there is a wide range of differing treatment options each with their own inherent strengths and weaknesses. This has required a multidisciplinary approach for many therapies, particularly the newer ones, requiring input from medical experts in different sub-specialties to encompass all aspects of the patient's current medical status in order to select the optimal treatment pathway.
- The need to understand and respect patients' values, goals, needs and financial situation, and engage them in an informative process of treatment options and shared decision-making
- Requirements related to each patient's disease, as well as the specific risks vs the benefits of the treatment, needs to be assessed by a multidisciplinary team. This assessment will be influenced by local capabilities that may change with time.

The AANMS is of the position that the development of skills and expertise in theranostics is necessary for its safe and effective use in a clinical setting and that these should also be

maintained through life-long learning. A multidisciplinary approach to patient selection, management and administration of the therapy is a key component of theranostic treatments.

Purpose and scope

1. This document sets out requirements to underpin delivery of high quality theranostic services in Australia and New Zealand.
2. These requirements should apply to all Specialists and sites participating in Australia and New Zealand.
3. Recommendations are for initial training as well as for measures to assure ongoing currency of practice are included.

Definitions:

AANMS	Australasian Association of Nuclear Medicine Specialist
CJCT	Committee for Joint College Training
RACP	Royal Australasian College of Physicians
RANZCR	Royal Australian and New Zealand College of Radiologists
Theranostics	The use of a radiopharmaceutical for both diagnosis and therapy
Molecular imaging	The visualization, characterization, and measurement of biological processes at the molecular and cellular levels
Radionuclide therapy	A treatment where a radionuclide is delivered via a cell targeting molecule
MDT	Multidisciplinary Team

Changes to this policy:

This policy is subject to a three yearly review and endorsement by the Nuclear Medicine CJCT and the AANMS Board. However, the AANMS Theranostics Working Group may amend this Policy at any time for endorsement.

Introduction

Theranostics is a rapidly evolving field whereby a diagnostic imaging test is performed with an agent that can also be utilised for therapy. Specifically, this involves a molecular imaging scan performed with the same radiopharmaceutical used in the therapy, or a diagnostic radiopharmaceutical with similar biodistribution characteristics as the targeted radiotherapeutic agent. The diagnostic scan is used to detect, locate, and characterise tumours, as well as to quantify tumour and normal tissue uptake of the radiopharmaceutical to guide therapy and minimise side effects.

Theranostics application in radionuclide therapy is not a new concept. Radioiodine (I-131) has been used for the diagnosis and treatment of thyroid cancer since the 1940s. Examples of established, new, and emerging radionuclide therapies that emphasise the importance and use of this treatment technique in the coming years are listed below. NB: This is not a comprehensive list.

- The original theranostic agent, ^{131}Iodine for managing and treating thyroid cancer informed by [^{123}I], [^{131}I] imaging or [^{124}I] PET
- [^{153}Sm] Samarium (Lexidronam) and [^{89}Sr]Strontium for bone pain of metastatic cancer, informed by [^{99m}Tc]Tc-MDP or [^{18}F] NaF PET bone scan
- [^{223}Ra] Radium therapy for metastatic prostate cancer, and other bone cancers informed by a [^{99m}Tc]Tc MDP or [^{18}F]NaF PET bone scan
- Iobenguane[^{131}I] MIBG for adult and paediatric patients with MIBG scan-positive, unresectable, locally advanced or metastatic pheochromocytoma, paraganglioma or neuroblastoma who require systemic anticancer therapy, with the suitability for treatment informed by imaging with the same agent
- Lutetium-labelled or Yttrium-labelled somatostatin analogue (e.g. [^{177}Lu]Lutetium DOTATATE or [^{90}Y]Yttrium DOTATATE (or equivalent ligand) therapy for neuroendocrine tumours and other tumours expressing somatostatin receptors - informed by somatostatin imaging (e.g. [^{68}Ga]Gallium DOTATATE PET)
- Lutetium-labelled or other radiolabelled PSMA targeting radiopharmaceutical therapy for prostate cancer and other tumours expressing PSMA—informed by PSMA PET imaging (e.g., [^{68}Ga] Gallium-HBED-CC-PSMA and [^{18}F] DCFPyL PSMA)
- Liver directed therapy with ^{90}Y-microspheres, informed by ^{99m}Tc-MAA studies
- Investigational radiolabelled antibodies to targets, informed by dosimetry using a diagnostic scan of similarly labelled antibodies
- Investigational alpha emitting therapeutics targeting a variety of targets including PSMA, informed by a PSMA targeted PET

Prerequisites for Theranostics

A) Qualified Theranostic Nuclear Medicine Specialist

Initial consultation

The patient's managing specialist (medical oncologist usually) would refer the patient for consultation with a nuclear medicine specialist (preferably the accredited treating Theranostics specialist) for consideration of therapy. The clinical consultation is an essential step for proper evaluation of a patient's suitability for radionuclide therapy. This requires a full assessment of the patient's medical condition, in collaboration with the managing specialist, to inform the decision whether to proceed with radionuclide therapy.

For theranostic procedures, molecular targeting is required. This requires the appropriate molecular imaging study for the theranostic agent to be performed in order to demonstrate the required target is present on the tumour without excessive unwanted binding to normal tissues. This scan underpins the decision making process regarding the appropriateness of radionuclide therapy for each patient.

The imaging must be performed within a recent time frame sufficient to minimise any chance that the disease may have developed into a non-avid variant subsequent to performance of the diagnostic study. This period will vary depending upon the patient's clinical context and the theranostic agent. Review of prior imaging should include assessment of all lesions on cross-sectional molecular and conventional imaging and evaluation of any unexpected distribution of radiopharmaceutical in normal organs or tumour sites that could increase the risk of adverse effects. Review of contemporaneous and prior conventional imaging across multiple modalities may require collaboration with other imaging specialists. This enables accurate and shared discussion of all imaging findings with the patient and the multi-disciplinary team (MDT).

This initial nuclear medicine consultation must be performed by a nuclear medicine specialist who is experienced and credentialed in interpreting PET/CT and SPECT/CT, and when required, with access to qualified Nuclear Medicine Physicists and appropriate software to permit prospective dosimetry, as required.

A complete medical and surgical history with attention to tolerance and response to prior treatments, allergies and medications is also essential. It is important to consider the other treatments previously given for the disease, particularly prior treatments which might impact the efficacy and/or toxicity of radiopharmaceutical therapy. This includes but is not limited to prior chemotherapy, surgery, external beam radiotherapy, brachytherapy, immunotherapy or prior radiopharmaceutical therapies.

A focused physical exam is also essential to assess performance status and co-morbidities, and appropriateness of the radiopharmaceutical. The patient's ability to tolerate therapies (ECOG status) needs to be assessed and will inform selection of safest and most tolerable therapies.

Review of imaging and pathology results in a formal and minuted MDT meeting is essential for certain therapies, particularly but not limited to: radiolabelled somatostatin analogues for the treatment of neuroendocrine tumours (NETs); newer therapies currently such as lutetium PSMA; and those therapies with higher risks such as alpha emitters. MDT meetings should be of such calibre to that established by Cancer Australia. These types of patients and therapies described above, as well as complex patients with co-morbidities require formal MDT review to assess and prioritise the therapeutic options available with the referring physician and other relevant specialists including radiation oncologists, oncologists, surgeons, diagnostic and interventional radiologists as required. Correspondence from these MDT meetings must be communicated formally to the patient's GP, and all relevant treating specialists, which may include those inside or outside the institution administering the theranostic treatment.

Following this, the theranostics specialist will discuss the recommendations of the MDT with the patient, explaining the rationale for a specific radionuclide treatment as well as advantages and disadvantages. If treatment is recommended, the patient must be advised of the potential side effects and complications, management of the side effects and any complications, the practical aspects and logistics of the radiopharmaceutical treatment, costs and radiation protection issues for the patient and family members. Once fully informed, the patient can decide if he/she will proceed with treatment, and if so, written informed consent is obtained and entered into the medical record.

Follow-up Assessment

The patient typically should have a follow-up appointment with the treating theranostics specialist according to local institutional practice, with imaging and pathology results as needed, to determine whether the patient remains suitable for further cycles of radionuclide therapy, and if so, whether any dose modifications are required. MDT discussion is required at not only treatment onset, but all seminal stages of treatment (particularly premature cessation and any complications), and may be required to consider and/or co-ordinate other therapies if appropriate.

The toxicity assessment and management of the radionuclide therapy will be performed by the treating physician and members of the managing team. Toxicity assessments may include acute and late toxicities; hence long-term follow-up is recommended to recognise and manage any late toxicities from radionuclide therapy. The assessment should be tailored to the radiotherapeutic agent used and the individual patient. Toxicity management may involve further diagnostic testing, medical management, and/or referral to other medical specialists as indicated. Acute and late toxicities, especially for new theranostic agents, should be formally documented at the MDT for further reference and discussion.

Tumour response assessments should be performed using appropriate imaging modalities, e.g. CT, MRI, bone scan, PET/CT scans, or pathological tests, e.g. specific tumour markers. Further assessment with receptor/ligand-based imaging of the radionuclide therapy used may be repeated to confirm the continued presence of the relevant target for therapy or significant tumour progression. These follow-up scans should always be performed at the same centre which performed the therapy, where possible, to allow quantitation of tracer

uptake compared to the pre-therapy scans, and personal review by the treating theranostic specialist. The response assessment and further management should be discussed with the patients managing clinician (e.g. medical oncologist) and/or the multidisciplinary team.

B) Appropriate Patient Selection

To be suitable for consideration of therapy with theranostic agents, the patient should:

- be referred by a specialist surgeon, medical or radiation oncologist, or other specialist physician, preferably the patient's primary treating physician or surgeon.
- the patient should be at a clinical stage whereby the theranostic therapy being considered is the best possible treatment for them relative to other available treatment options – to ensure no treatment opportunity, or fiscal, loss to the patient. When speaking to the patient, all available and reasonable treatment options should be discussed, and the relative risks and advantages put to the patient so that they can make a full informed decision.
- be reviewed by an appropriately credentialled specialist in theranostics.
- have adequate binding of the theranostic agent to their tumour demonstrated on ancillary imaging.
- where appropriate, have evidence that all or most of their tumour is able to bind the relevant agent. Dual radiotracer studies incorporating a metabolic agent (typically FDG) may be required to assess for the presence of disease that will be unresponsive to treatment due to lack of expression of the appropriate target.
- have a suitable balance between likely treatment response and adverse effects.

C) Individualised Treatment plan

Multidisciplinary Team

The Multidisciplinary Team (MDT) environment is critical to the management of most patients, particularly when utilising new generation theranostic compounds. These patients often have complex care needs associated with metastatic inoperable disease, requiring coordination of care and planning with the treating cancer specialists including medical oncologist, radiation oncologist, surgeon and endocrinologists. This may include the use of radiosensitising chemotherapy, timing of adjunctive therapies (eg somatostatin analogue therapy for NETs), effective combination treatments, external beam radiotherapy or other directed therapies such as transarterial chemoembolization (TACE).

It is expected that the theranostic specialist will regularly attend and present patients for discussion, and/or or participate in discussions of other patients at relevant multidisciplinary meetings. Such regular attendance is crucial for the theranostic specialist to develop a thorough understanding of the disease to be treated, maintain currency with other therapies available for the disease, educate other specialist members of the MDT on the benefits and risks of radionuclide therapy and its place in the management algorithm, and to advocate for radionuclide therapy where appropriate.

It should be recognised that there are many available treatments for different cancers. Choosing an appropriate therapy for the stage of the disease (early or late stage) and the optimal sequencing of treatments will impact the depth and duration of treatment for each patient. Every effort must be made by the theranostics specialist to ensure that if a theranostics treatment is offered to a patient, then there is scientific evidence to prove that it is the best treatment for the patient at their stage of disease. Furthermore, it should be used in conjunction with adjuvant therapies or combination therapies that best treat the patient. This is a complex decision and should be done in a multidisciplinary setting, with full and open disclosure to the patient of all available treatment options, risks and expected benefits.

For newer therapies and complex therapies, such as lutetium PMSA, complex thyroid cancer therapies, and those with more severe side effects, such as alpha emitters, the MDT should be compliant with standards of MDT set by Cancer Australia.

Side effects

Awareness and preparation for rare, but potentially life-threatening, complications is necessary. For example, specific patients at risk of hormonal crises (e.g. carcinoid syndrome, insulinoma, VIPoma and phaeochromocytoma / paraganglioma) may require inpatient admission and proactive early referral to an endocrinologist to minimise the risk of complications. Full disclosure of long-term risks relevant to the proposed treatment, such as myelodysplasia or renal impairment, should also be undertaken with the patient.

Management and minimising of adverse outcomes

Therapy should be provided at nuclear medicine facilities that have expertise in assessing, managing and administering radionuclide therapy to patients.

The patient's treatment plan may need to be adjusted in regard to dose administered, e.g. frequency of administration and use of renoprotective or sialoprotective agents. or other interventions to reduce adverse effects.

Dosimetry

For selected patients, dosimetric quantification enables the potential for personalised optimal radiopharmaceutical treatment compared to more conventional approaches of empiric dose targeted radionuclide therapies. This allows for the optimal activity to be administered to achieve sufficient dose to target while considering dose to non-target organs. This should be performed by suitably qualified personnel (see below).

Post-Therapy Imaging

The ability to "see what you treat" is a key advantage of theranostics and should be undertaken routinely in all radionuclides for which it is possible. Most radionuclide therapies in clinical use are amenable to post-therapy imaging with SPECT/CT or PET/CT.

Post therapy imaging allows for:

- confirming expected biodistribution

- assessment of uptake at target sites
- correlation for clinical symptoms
- unexpected further sites of disease
- assessment of disease progression
- quantification of response for some agents
- understanding the principles of dosimetry

Current novel theranostics may include one post-administration image of the therapeutic distribution. This serves to demonstrate uptake with the expected biodistribution and helps to ensure that the administration was not extravasated at the injection site. These are typically whole-body images on a gamma camera, either planar or total body SPECT/CT. The images may also serve as an interval surrogate for the PET scan that would have been performed prior to commencing treatment.

More detailed imaging can be utilised for individualised dosimetry, but not always necessary. This would typically require imaging at 3-4 time points post-administration over a number of days. A typical imaging protocol might include imaging at 4 hours, 24 hours and 96-120 hours after administration of the radionuclide therapy. The imaging should be quantitative, either 2-D geometric mean planar images, all or fully 3-D SPECT/CT. This may be useful in the early phases of introducing a new theranostic treatment where organs at risk can be imaged and effective dose to the organs measured directly. Kidneys and bone marrow will always be of interest with radiopharmaceuticals that are renally eliminated/excreted. For therapies that are predominantly sequestrated in the liver (e.g. monoclonal antibodies), the kidneys may be of less concern and liver and bowel of heightened interest in terms of effective dose from the radionuclide therapy.

While dosimetry calculations are often performed by nuclear medicine physicists, the nuclear medicine specialist should have a firm grasp of the techniques involved and the limitations thereof and be able to perform this in the absence of an on-site physicist.

D) Departmental requirements

Laboratory Requirements (including personnel and site requirements if manufacturing onsite)

Therapeutic radiopharmaceuticals should be manufactured by a qualified radiopharmaceutical scientist/radiochemist. Where appropriate, and when making the theranostic radiopharmaceutical onsite, staff should be appropriately trained in both radiopharmaceutical manufacturing and quality control testing, and this should be performed in an appropriate environment. Good radiopharmaceutical practice should be adopted wherever possible for continued process control and high quality standards. Where applicable, radiopharmaceuticals should be prepared according to regulatory and monograph guidelines.

If made onsite, a documented procedure (e.g. standard operating procedure or work instruction) describing the entire process for manufacture specific to the infrastructure on-site should be available and staff training and compliance to this procedure should be

recorded. Deviations to this procedure should be documented according to site protocols. The process to manufacture radiopharmaceuticals may involve manual processes or the use of an automated module (running a validated sequence) using reagents, hardware and consumables that are supplied from commercial vendors or prepared on-site with appropriate supporting documentation. All consumables should be purchased from reputable suppliers, who can provide documentation to support a minimum quality standard for at least all product-contact items.

A batch record or worksheet unique to each batch of radiopharmaceutical should document the process inputs and consumables with traceability and expiry of stock used (where relevant). Data produced relevant to the radiopharmaceutical batch (e.g. product activity, volume, expiry, formulation) should also be recorded along with the quality control tests (with test methods referenced), pre-defined acceptance criteria and test results specific to each batch. Copies of supporting analytical data relevant to quality control testing should be retained.

All equipment used in the manufacture and quality control testing of radiopharmaceuticals should be qualified at installation and routine checks to ensure reliability in operation. Maintenance and use logs for critical equipment would also be considered good practice.

Process and product data should be collated and trended routinely to ensure process control. Resourcing should allow for separation of the manufacture, quality control and quality assurance review tasks by different trained staff. If not possible final review of product quality remains the responsibility of the administering Theranostic specialist.

A risk-based approach to validation should be completed prior to preparing radiopharmaceuticals for human use. This would include trained staff preparing a number of consecutive batches of each radiopharmaceutical according to the site documented procedures, which simulate conditions and maximum radioactivity limits for each process. Each batch must pass all pre-defined acceptance criteria for all quality control tests. The number of batches made is determined by a risk assessment relevant to each site and is designed to provide confidence in the process and also product quality. The expiry assigned to a radiopharmaceutical is specific to each radiopharmaceutical and site, as determined from quality control testing and stability assessment of the product across all validation batches.

Laboratory design should consider both the facility environment as well as staff safety to minimise radiation exposure in radiopharmaceutical preparation, quality control and patient dose preparation. The facility environment and corresponding infrastructure should at minimum have capacity for sterile processes, including sterile filtration of the final radiopharmaceutical product.

Medical Physics Requirements (including personnel, radiation safety and dosimetry)

The role of the medical physicist in the delivery of radionuclide therapy is at multiple levels. The highest level is to ensure good radiation protection practice both within the department and in the general population. The medical physicist is usually consulted (or develops appropriate SOP's for medical radiation scientists or theranostic trained medical radiation

scientists) prior to treatment to verify that the patient does not present a potential source of excess radiation exposure to staff and to the general public and to assess any potential complications that may arise after the treatment (e.g., incontinence). For treatments that are given as outpatients, the medical physicist's advice is used to decide when the patient can be released from the control facility under which the therapy is given to either their home, another residence or back to the hospital ward. Once released, the patient needs to be aware of the radiation protection guidelines that they should follow and for what period of time. This advice can be given by a trained medical physicist or medical radiation scientist or theranostics medical specialist.

The medical physicist/radiation safety officer should be available for consult during the delivery of high doses (such as most therapeutic doses) of potentially toxic radiopharmaceuticals, or have been involved in the development of SOP documentation to deal with the delivery of high doses or potentially toxic radiopharmaceuticals. Any departure from normal procedures, such as a spill or an extravasated injection, will require an objective assessment of the likely implications and expert knowledge of the procedures that should be undertaken to mitigate the effect on patients. This should be managed by appropriately trained staff such as medical physicists, medical radiation scientists (technologists) or theranostics medical specialists.

The medical physicist, theranostic medical specialist, or trained medical radiation scientist, is also expected to understand the technical and instrumentation chain from the drawing up of the treatment radiopharmaceutical and the accuracy of its calibration through to the appropriate handling of any unsealed sources of radiation liberated after the treatment. The consulting physicist is an important resource in ensuring the nuclear medicine specialist, medical radiation scientist, and multidisciplinary team have access to the most relevant and current advice on the safe administration of unsealed radioisotopes in each patient and play a critical role in assisting with dosimetry and dose planning.

In Australia and New Zealand, the above tasks should be under the supervision[1] (active or through the use of standard operating procedures) of a qualified Nuclear Medicine Medical Physicist accredited with the ACPSEM.

Nuclear Medicine Technologists (NMT) / Medical Radiation Scientists (MRS)

The role of the NMT/MRS in the delivery of radionuclide therapy is at multiple levels, and will vary within departments and states. They may be responsible for drawing up radiopharmaceuticals and measuring their activity before and after treatment. This will be done either under the supervision of a theranostics specialist, or in conjunction with an appropriate standard operating procedures (SOP). Technologists will perform post-therapy imaging as per site specific protocols.

The technologists will have important roles in supervising the patient before, during and after treatment and may coordinate necessary care arrangements. They may also assist the NM

[1] Definition as per ACPSEM - *Active supervision* by a credentialed nuclear medicine physicist can be direct supervision (meaning being present in person or personally performing) or consultative supervision (meaning supervision of other suitably trained individuals involved in the programme).

Medical Physicist in dosimetry estimations as required, and particularly if the consulting physicist is not physically onsite. They may also be involved in ensuring good radiation protection practice both within the department and in the general population under the supervision of SOP developed by the responsible medical physicist, or direct supervision.

For treatments that are given as outpatients, the technologist may advise when the patient can be released from the control facility under which the therapy is given to either their home, another residence or back to the hospital ward, using SOPs developed by an appropriately trained medical physicist and in conjunction with the Theranostics medical specialist. Once released, the patient needs to be aware of the radiation protection guidelines that they should follow and for what period of time. This advice can be given by a trained medical physicist, NMT/MRS, or Theranostics medical specialist and should always be based on SOPs held by the department.

Other ancillary staff (eg. nursing)

Sites should have specific guidelines for each radiotherapeutic administration, with site specific nursing and technologist protocols. The nursing staff will often have important roles in supervising the patient before, during and after treatment and may coordinate necessary care arrangements.

All nursing staff caring for patients having radionuclide therapy should be trained in radiation safety and be required to wear a dosimeter to record radiation exposure and be knowledgeable on principles of radiation protection. Nursing staff will also administer required pre-medications for the specific radionuclide therapy and any necessary preparatory infusions (eg. amino acids).

Departmental Documentation

All departments should have safe standard operating procedure (SOP) guidelines for delivery of therapeutic radionuclides. All facilities involved in the delivery of therapeutic radionuclides should have immediately to hand appropriate protocols and procedures documented to ensure absolute safety of staff, patients and the general public.

These should include at a minimum:

1. SOP for safe administration of therapeutic radionuclides including appropriate drawing up of dose, double checking of dose, confirmation of all necessary QC release, and time out procedures at the patient's side, and confirmation of patency of intravenous administration if the therapeutic is intravenous.
2. SOP for management of radiation spills and contamination
3. SOP for radiation safety advice to patients and carers based on the radiotherapeutic administered

4. SOP for the safe discharge of patients from the department after an administration of therapeutic radionuclide – this should also be developed based on the specific radionuclide administered

All SOP developed should be endorsed by both the Medical Physicist involved in the delivery of care at that site, and the Theranostics medical specialists directly responsible for care at the facility.

Training and Accreditation

Performance of theranostic procedures requires competency in several areas. A detailed understanding of both the molecular imaging diagnostic scan as well as the therapeutic agent is required. Understanding the normal biodistribution of these agents, common pitfalls in interpretation and translating the diagnostic scan appearance into an appreciation of the likely efficacy of radionuclide therapy is considered essential. Practical experience in assessing these patients, managing therapy delivery and short- and long-term side effects is also critical to optimal service delivery and requires exposure to a sufficient volume of referrals and therapies. Training requirements for administration of basic I-131 therapy is covered in the Nuclear Medicine Advanced Training Program, but complex I-131 therapy and I-131 MIBG therapy is considered within this document.

A) Prerequisite credentials for Practice of Theranostics

The medical specialist seeking recognition as a Theranostics Specialist must be able to demonstrate evidence of one of the following prerequisites:

1. Fellow of the Royal Australasian College of Physicians (FRACP) with credentialing of nuclear medicine by the Committee of Joint College Training (CJCT) of the RACP and RANZCR; or

2. Fellow of RANZCR with credentialing of nuclear medicine by the Committee of Joint College Training (CJCT) of the RACP and RANZCR.

B) Committee for Theranostics Training

The committee will aim to promote a collaborative and consistent model of theranostic training and service delivery in Australia and New Zealand.

The Committee's role is to:

- Formulate and review guidelines for training in theranostics
- Formulate and review guidelines for training courses in theranostics (these do not supplant the need for experiential training)
- Provide certification of satisfactory completion of theranostics training
- Maintain and publish a web-based register of recognised theranostic specialists

The Nuclear Medicine CJCT will be responsible for the prospective approval of training, and then certification upon satisfactory completion of training.

C) Training Requirements

Prospective:

All medical specialists seeking to establish proficiency in Theranostics are required to achieve the following skills during their training program:

- Understanding of the physiology and radiation physics employed in Theranostics, including understanding of the radiobiology of therapeutic nuclear medicine
- Patient selection (including molecular imaging assessment and correlation) and preparation
- Understanding the indications, contraindications, and management of adverse events
- Radiation protection of patient, staff and general public

Acknowledging that theranostics is an evolving field, at the time of writing, it is recommended that training in both neuroendocrine and prostate theranostics is undertaken.

The *prospective* training program must comprise a mix of both didactic and supervised clinical practice:

- Patients selection with direct expert supervision
- Multidisciplinary case discussion
- Documented evaluation and administration of novel radionuclide therapies
- Experience with a range of therapies is required, with TWO different therapies as a minimum.
- Theranostic training may require an additional 6 months of training at an accredited site(s) after completing initial two years of core nuclear medicine training. Some training sites may require rotation to multiple facilities.
- Training at non-accredited sites (e.g. overseas centres) requires *prior* approval
- Participation in AANMS Theranostics Course for initial accreditation

General Accreditation

Completion of the minimum training requirements and/or Legacy Provisions will qualify the applicant for *General Accreditation* allowing for participation in providing theranostic services.

Requirements are:

1. Experience with >50 therapies by initial consultations and/or administrations within the last 3 years
2. Participation in multidisciplinary discussion of >50 cases
3. Ongoing participation in relevant CPD activities (e.g. conferences, courses)

Advanced Accreditation

Practitioners who have extensive experience may apply for *Advanced Accreditation*. Advanced accredited specialists will be allowed to provide training and are a requirement for site accreditation.

Requirements are:

1. Clinical experience which encompasses >120 therapy initial consultations and/or administrations within the last 3 years
2. Participation in multidisciplinary discussion of >100 cases
3. Ongoing Participation in relevant CPD activities (e.g. conferences, courses)
4. Participation in recognised research in the field

Legacy provisions (Recognition of Prior Practice)

- Current practitioners eligible for theranostic accreditation should apply for recognition within 3 years and meet requirements for *General or Advanced Accreditation*.

- Practitioners with current expertise may apply for accreditation based on prior experience, with the above numbers acquired over 3 years.

D) Training Site Requirements

a) Staffing

- Minimum *Advanced Accredited* Theranostic Specialist onsite
- Theranostic accredited Nuclear Medicine Specialist onsite for all therapy administrations
- Nursing/technologist for therapy administration
- Qualified Radiopharmaceutical Scientist
- ACPSEM Accredited Medical Physics Specialist (Nuclear Medicine)/Radiation Safety Officer onsite

b) Protocols/procedures

- Site protocol manual including general provisions for administration of radionuclide therapies and for each specific therapy offered, including roles of medical, radiopharmacy, physicist, nursing and administrative staff
- Protocols for radiopharmaceutical dispensing, labelling and disposal.
- For sites with in-house manufacturing of radiopharmaceuticals, production and quality control processes to be documented in site protocols/procedure manuals, as per ARTnet certification processes

c) Multidisciplinary team

- Regular scheduled multidisciplinary team meetings which encompass all of the theranostic applications employed at that training site

d) Patient volume – These should be defined for a *training* site.

Training Application

A) Application Process

Upon completion of training in Theranostics, applicants must:

1. Compile their documentation to demonstrate evidence of their training according to the requirements in this document

2. Complete the application form and attach evidence of training, and application fee payment. The application fee will be kept to a minimum, applied to cover the basic costs of application review.

- Applicants are advised to submit applications only after careful consideration of the requirements
- Applications that fail to satisfy the requirements will be subject to a resubmission fee
- Please note that applications will not be processed until payment is received.

Further information is available from www.aanms.org.au