

## Theranostics Certification Fact Sheet

### August 2025

### What is the background to the proposed Theranostics Certification?

The rapid expansion in number, sophistication and efficacy of theranostic pairings has seen a corresponding increase in incorporation into mainstream treatment paradigms. Some agents have inherent pharmacologic activity and toxicity, which Theranostics practitioners should be aware of. Current research indicates that combination with immunotherapy and sophisticated radiosensitisers will be inevitable, with increasing body of evidence around the side effects of such combinations.

Nuclear medicine specialists are the experts in the use of radionuclide therapies. Whilst the use of these new generation of radionuclide treatments are similar in principle, it is imperative that specialists are aware of the increased complexity of assessment, administration and follow-up required for new generation theranostics.

This process is not confined to Australia. Similar guidelines have been formulated by the SNMMI, EANM and the IAEA. The AANMS considers that it is in the interest of Nuclear Medicine Specialists to be proactive. Therefore, the Theranostics Certification process is similar to that undertaken when PET/CT was introduced into clinical practice and obtaining certification for experience in PET/CT was required to enable nuclear medicine specialists to be recognised as fully trained in this area of nuclear medicine practice.

### How will it benefit NM patients and practitioners?

It will protect patients by ensuring that the practitioners providing the service are trained appropriately.

It also ensures the Nuclear Medicine Specialist maintains their pre-eminent role in the use of theranostics agents, by being able to image and treat appropriately, given the profession's familiarity with nuances in the science and the clinical radiobiology at the cellular level. This will also ensure that certified nuclear medicine specialists are recognised as key treating clinicians in a multidisciplinary approach to patient clinical care.

### What type of therapies can be included for certification?

Any two or more therapies used for malignant disease can be included – e.g. High dose I-131, Y-90, Sr-89, Sm-153, P-32, Lu-177, Ac-225 etc. Please note that relevant encounters are only those which relate to management of neoplasms. Treatment of benign conditions (e.g. I-131 for thyrotoxicosis) are not acceptable. It is important to note that this does not – and was never intended to – apply solely to Lu-177 agents.

### Must the numbers for certification only apply for therapies given in the last 3 years, or might a longer period be considered?

The certification concept was originally developed based on the flexible triennial basis used by several other organisations. The certifying committee is aware of the changes in oncology practice mandated by the COVID pandemic. There may be other personal factors which have affected practice (e.g. changes in employers, roles, leave etc). These will be taken into account when considering applications. Based on feedback, there will be some flexibility granted for the period of time in which the experience and number of cases can be stated.

To expedite the process and make it as fair and equitable as possible please submit the treatments which you consider meet the criteria, together with an outline of any circumstances which may have impacted upon scope and timeliness of experience. This will be considered in confidence by the Committee.

If a resubmission for additional information is required, you will not be charged again. However, a submission for advanced certification (for training) after following a submission for general certification will attract a fee.

Please note that initial, post-therapy, and follow-up consultations can be counted as individual encounters. Post-therapy scans not performed as part of a consultation cannot be claimed as experience. MDT discussions attended as part of nuclear medicine meetings can be counted toward required experience.

### Are sites being certified or only individual specialists?

At this time, only individuals are being certified. Sites are not being assessed except to the extent necessary to ensure that each practitioner is competent in providing the service (standard of care) as per the Theranostics Guidelines, no matter where they work. This is not intended to create 'silos' or 'centres of excellence'.

### Do currently practicing NM specialists need to do anything right now? What are the timelines for certification?

As stated in the initial communication there is no need for currently practicing NM specialists to do anything immediately. Licences and currently administered therapies are not affected. Whilst the AANMS is not sure what the future requirements will be for new therapies, this process is intended to ensure current practitioners have their experience recognised as the future evolves. The certification process will not affect claiming for or performing of items on the MBS as of 01 September 2023.

This legacy certification will be available until 2030, and submissions will be twice a year, in keeping with the CJCT meetings. Theranostics training will be prospectively incorporated into the revised nuclear medicine curriculum to be introduced as of 2026. This legacy process will therefore not be applicable to trainees entering the programme from this date. It will apply to trainees currently undertaking advanced training.

### Will certification be required for MBS eligibility now or in the future?

Certification provides exactly what is says: certification of an independent assessment of prior theranostic experience. The AANMS has no knowledge at present as to whether this will be linked to credentialling or MBS eligibility. This remains the province of Government. However, the AANMS believes in proactive support of members and future developments in practice.

### Will certification need to be renewed?

This certification will be similar to PET certification and will not need to be renewed.

### Why are there two levels of certification?

The general level is for those who have done a minimum number of therapies, without fulfilling the criteria for the advanced level (which qualifies for teaching). Even if you have not fulfilled all the criteria for the advanced level, feel free to submit with an explanation, and it will be taken into consideration. Should your advanced level application be declined, a general certification will be issued if merited, and you can resubmit at a later date.

**It is realised that situations or questions not covered in this general Fact Sheet will arise. Please address these to [theranostics.certification@aanms.org.au](mailto:theranostics.certification@aanms.org.au)**