

Australasian Association of Nuclear Medicine Specialists Position Statement: Developing A Sovereign Nuclear Medicine Industry August 2022

Position

- Nuclear medicine is a rapidly growing area of medicine which can treat many serious health conditions, including the five leading causes of death in Australia: cancer, dementia, stroke, heart and lung diseases
- For context - on average every Australian will require more than two nuclear medicine procedures during their lifetime; this results in over 700,000 nuclear medicine services being delivered in Australia each year
- Australia has the potential to develop a world-leading nuclear medicine industry, providing both health and economic benefits to the Australian community
- This potential is put at risk due to Australia's aging and inadequate nuclear medicine infrastructure
- Upgrading Australia's nuclear medicine infrastructure would increase access to nuclear medicine services for Australians and provide export opportunities to meet growing demand worldwide for nuclear medicine
- This would ensure Australia is well-positioned to take full advantage of the medical advances in this area, including anticipated growth in theranostics, a form of precision cancer treatment in which Australia is a world leader

Background

Importance of nuclear medicine

Nuclear medicine is a rapidly growing area of medicine which can treat many serious health conditions, including the five leading causes of death in Australia: cancer, dementia, stroke, heart and lung diseases.

Nuclear medicine involves the use of small amounts of unsealed radioactive materials to diagnose and treat disease. It can be used to treat a range of health conditions, including the five leading causes of death in Australia: Heart disease, dementia, stroke, cancer and lung disease. On average, every Australian will require two nuclear medicine procedures during their lifetime. Currently over 700,000 nuclear medicine services are delivered in Australia every year, with ANSTO radioisotopes providing 10,000-12,000 nuclear medicine procedures that benefit Australians each week¹.

Nuclear medicine has been undergoing rapid growth of its available technologies, particularly positron emission tomography (PET) imaging, which has become integral to patient management in oncology and is now expanding into other fields, such as neurology, infection and inflammation.

¹ ANSTO Available online: <https://www.ansto.gov.au/education/nuclear-facts>

Therapeutic options provided by nuclear medicine — known as theranostics — are also undergoing rapid expansion. Theranostics is an exciting field of precision medicine for the treatment of some forms of cancer. This combination of diagnostic and therapeutic nuclear medicine expertise services patients with conditions that were previously untreatable, while limiting side effects and offering treatment to people who are unable to undergo chemotherapy or other standard oncology.

With 151,000 new cancer diagnoses in Australia in 2021², and an expected rise in late-stage cancer diagnoses due to the CoVID-19 pandemic, theranostics has a significant role to play in delivering the best outcomes for Australian cancer patients.

Australia's nuclear medicine advantages

Australia's natural resources, existing nuclear infrastructure and strong health and medical research sectors mean it could develop a world-leading nuclear medicine industry.

Australia is a globally recognised leader in nuclear medicine practice, research and innovation, particularly in the field of theranostics. Australian researchers are the lead authors on multiple highly regarded theranostics papers internationally and lead the world in the Lancet Oncology Commission on Theranostics, together with the World Health Organisation.

Australia also has a strong nuclear medicine industry and is well-placed to establish sovereign production of nuclear medicine supplies due to its ready access to raw materials and historical investment in production facilities. Australia possesses around one third of the world's uranium resources, giving domestic medical isotope producers direct access to the chemical element used to power nuclear reactors.

The Australian Nuclear Science and Technology Organisation (ANSTO)'s existing nuclear reactor at Lucas Heights, produces around 80 per cent of Australia's nuclear medicine isotopes, and will act as an important hub for future facilities producing nuclear medicine supplies. However, continued resources are required to both maintain and sustain the high quality output from ANSTO.

Challenges in Australia's nuclear medicine sector

Australia's ageing and inadequate nuclear medicine infrastructure is not able to meet our current needs for radioactive materials.

Nuclear medicine uses radioactive materials produced by nuclear reactors and particle accelerators (cyclotrons). Australia has the potential to produce sufficient radioactive materials for domestic nuclear medicine use and for export internationally.

However, Australia is currently reliant on international sources for some key nuclear medicine supplies, despite the OPAL reactor at ANSTO producing some raw material (ie, Mo-99). This is despite nuclear medicine being [listed by the Federal government](#) as a critical technology in Australia's national interest.

This reliance on overseas supply puts Australia's access to crucial radionuclides at significant risk whenever there is disruption to standard air travel, extreme weather events, natural disasters, and international conflict. This directly affects patient care by delaying access to imaging and therapeutics and threatens industry viability through frequent periods where equipment is inactive.

² Australian Institute of Health and Welfare, *Cancer in Australia 2021*. Available online: <https://www.aihw.gov.au/reports/cancer/cancer-in-australia-2021/summary>

These strains on Australia's nuclear medicine sector exacerbate existing challenges, particularly relating to the affordability of care. Nuclear medicine costs have increased significantly over time, largely driven by the price of the radioactive isotopes required for imaging and therapy. Rather than increasing public support, successive governments have maintained a Medicare Benefits Schedule (MBS) indexation freeze that was introduced in 1998 and nuclear medicine remains the sole remaining imaging modality which has not been indexed for >20 years. With radioactive tracers alone constituting 25 to 40 per cent of the MBS rebate, this is an unsustainable model that is forcing many patients into the public hospital sector due to cessation of nuclear medicine services in the private sector.

The role of ANSTO

ANSTO is a key pillar for delivering nuclear medicine, including theranostics, in Australia and a contributor to the development of an export industry, but ageing infrastructure have limited the production capacity and, at times, reliability of ANSTO's facilities. In the context of a global shortage for a key isotope in nuclear medicine activities, these limitations can bring the domestic nuclear medicine sector to a standstill, while preventing Australia from gaining export income by meeting the international shortfall.

Nuclear medicine relies heavily on the availability of ^{99m}Techetium for the majority of its non-PET imaging. This isotope is produced through the OPAL reactor at ANSTO's Lucas Height's facility, which produces molybdenum-99 (Mo-99) which is the precursor for the production of ^{99m}Techetium, the most used radionuclide in nuclear medicine.

ANSTO produces and supplies more than 50% of the domestic requirement of I-131 used to treat hyperthyroidism and thyroid cancer, which is increasing in incidence. It also produces and supplies Lu-177 non-carrier-added (n.c.a) that is used as a theranostic agent for neuroendocrine tumours and metastatic castrate resistant prostate cancer. Though Lu-177 is currently used in clinical trial setting and special access scheme only, the demand for this isotope is expected to significantly increase in the coming years, as its role in the treatment paradigm of these cancers are constantly being validated in large phase 3 trials, both locally and internationally. ANSTO is also the only commercial agency that supplies niche but clinically important products like I-123 MIBG and I-131 MIBG that is mainly required by paediatric patients.

As the theranostic field grows, ANSTO will be an important partner to develop and manufacture new radioisotopes for the future, to ensure that continued access and availability of the most effective radionuclide treatment is made available for Australian patients. Both Lutetium PSMA and Lutetium DOTA-TATE have both been approved by the FDA.

Over the past five years ANSTO has experienced a number of interruptions to production, including local production issues in the ageing production facility (non-OPAL), and limited international flights available to transport radionuclides (which was exacerbated during the peak of the pandemic). This has resulted in significant disruptions, with patient treatment at times being cancelled at the last minute and/or extensive waiting lists eventuating.

Recommendations

Australia's natural resources, existing nuclear infrastructure and strong health and medical research sectors provide the potential to build on our sovereign capability and establish a truly world-leading nuclear medicine industry.

Long term, strategic bipartisan support is needed to increase the nuclear medicine capability of ANSTO and enable Australia to capitalise on our inherent advantages and secure supply of this critical technology for Australian patients, which is the mandate of ANSTO.

This would deliver the following benefits:

- **Secure the supply** of radioactive isotopes to nuclear medicine services in Australia, ensuring timely treatment for patients and continued viability of the sector.
- **Reduce costs** of nuclear medicine treatment, limiting the out-of-pocket costs to patients and making the delivery of nuclear medicine services, including theranostics, a practical option for healthcare providers.
- **Position Australia to export** nuclear medicine supplies, securing international income to support the long-term sustainability of Australia's nuclear medicine industry in Australia and regionally.
- **Provide more onshore, highly skilled jobs** such as nuclear medicine practitioners, researchers and developers, which adds to the sustainability of this crucial technology.

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