

FNCA Ministerial Level Meeting 2022

Country Report – Australia

This year has seen a significant resumption of pre-COVID activity in the nuclear space, both globally and in Australia. Despite some continuing legacies from the disruptions of previous years, Australia's nuclear medicine facilities are producing and supplying at reliable operational levels. Australia also is progressing plans for the establishment of a National Radioactive Waste Management Facility, and has successfully undertaken an operation to repatriate intermediate-level waste that was reprocessed in the United Kingdom.

1. National Radioactive Waste Management Facility

On 29 November 2021, a declaration was made under the *National Radioactive Waste Management Act 2012* (Cth) to make a volunteered site in the state of South Australia the site for a National Radioactive Waste Management Facility (NRWMF). The acquired site, situated near Kimba in the State's mid-North, is another important step in the establishment of this crucial piece of national infrastructure and helps to secure the future of Australia's nuclear medicine industry and the country's nuclear research capability. The NRWMF will provide for the disposal of Australia's low-level waste and the interim storage of intermediate-level waste.

2. Nuclear Medicine Supply

Nuclear medicine supply in Australia no longer is affected by the COVID constraints of 2020-21 and day-to-day domestic supply and production has returned to normal. The recently commissioned ANSTO Nuclear Medicine facility is operating at expected levels of production and Building 23 continues to supply as required. In line with pre-COVID activity, Australia continues to import some essential niche nuclear medicine products from international suppliers.

Most critically, iodine-123MIBG, which is used in the diagnosis and treatment of paediatric neuroblastoma (cancer in the nerve cells), is imported from Japan. As Australia does not produce iodine-123MIBG, this arrangement will remain in place indefinitely. Although COVID continues to have lasting global impacts on freighting costs, these have remained largely under control for ANSTO. Previous COVID-related scheduling issues are now manageable, due to the increase in international and domestic flight availability.

3. Nuclear Medicine Production

The Australian Government has launched a project for the design of a new nuclear medicine manufacturing facility, to be built at the Australian Nuclear Science and Technology Organisation (ANSTO), in Southern Sydney. This commitment is the first step of a multi-phased approach to replacing ANSTO's current nuclear medicine manufacturing facility (known in the industry as Building 23) with a new, world-leading design. Phase 1 of the project will run until the end of the 2022-2023 financial year. It is estimated the project will take approximately eight to nine years to bring to fruition.

The new facility will meet domestic demand for technetium-, lutetium-, and iodine-based products, and will have the flexibility to respond to market and technological changes. The modern design will enable greater process automation than is possible with the existing technology, leading to improvements in efficiency and quality, and, most importantly, to the highest levels of production safety. The project also will support radiopharmaceutical research and development, accommodate future advances in nuclear medicine technology, and contribute to research translation and medical industry collaboration.

4. ANSTO Update

As Australia's leader in nuclear science, ANSTO has extensive experience in the advanced manufacturing of nuclear medicines for the diagnosis and treatment of a range of diseases including cancer. ANSTO produces 80 per cent of Australia's nuclear medicines used for the diagnosis, staging, and treatment of diseases, including cancer. ANSTO also supplies over 50 per cent of the world's requirements for irradiated silicon and plays a key role in support for Australia's critical minerals strategy, which is aimed at ensuring greater self-reliance and diversity of international supply of critical minerals.

The new Micro Computed Tomography (MCT) beamline is the first instrument to become operational as part of the \$94 million Project BRIGHT program, which will see the completion of eight new beamlines at ANSTO's Australian Synchrotron, which is in Melbourne. The BRIGHT beamlines will greatly expand the investigative power and throughput of the Australian Synchrotron with new capabilities not covered by existing instruments.

Despite a series of setback and delays due to COVID-19, a team of instrument scientists, engineers, project officers, and technicians achieved first light on MCT on 21 November 2021. Micro-CT uses X-rays produced by the Australian Synchrotron to reveal a detailed picture of the inside of an object, slice by slice, non-destructively. Suitable for sub-micron scale studies, MCT complements the existing Imaging and Medical Beamline, which is used for larger objects. The future development of MCT will extend the imaging capabilities to nano-CT on smaller samples.

ANSTO also has been contracted as the Australian manufacturing partner of an innovative, non-invasive treatment for non-melanoma skin cancer, which has been developed by Germany company, OncoBeta. OncoBeta's epidermal radioisotope therapy already has been used to successfully treat 1900 non-melanoma-skin-cancer lesions affecting patients around the world.

The innovative, non-invasive therapy utilises the radioisotope rhenium-188 and is applied only to the area requiring treatment, sparing healthy tissue. ANSTO will be manufacturing and supplying the rhenium-188 to all study centres in Australia.

Further, Applied Molecular Therapies (AMT) has announced a successful Therapeutic Goods Administration licence upgrade for the Good Manufacturing Practice manufacture of an emerging prostate cancer therapy, following the launch of a new joint venture between Cyclotek and ANSTO. The therapy, which involves lutetium-177, is a molecular targeted radiopharmaceutical that binds to the Prostate Specific Membrane Antigen (PSMA) in men living with prostate cancer. Prostate

cancer is the third most common cause of cancer death in Australia and it is estimated that more than 18,000 new cases of prostate cancer will be diagnosed in Australia this year.

In recent years, much attention has focused on lutetium-177 PSMA as a treatment for late-stage prostate cancer with several Australian and international trials providing evidence that this therapy improves clinical outcomes and can prolong survival.

5. Radiation detection

In October 2021, ANSTO's proprietary advanced radiation imaging solution, CORIS360, was awarded two Gold Good Design Awards from Good Design Australia, winning in the categories of Product Design/ Commercial and Industrial as well as Engineering Design.

CORIS360 is a portable device developed by ANSTO that can pinpoint the location of radiation sources and produce an image of them, both quickly and accurately. Other technologies have a limited energy range and/ or a limited field of view.

Following seven years of research and development, including five years of operational testing, CORIS360 was launched in late 2020 and has been sold both domestically and internationally to government agencies (including in the defence and military sectors) and to specialist research organisations. Its key design features include remote operation, ease of use, faster imaging, future-proofing, and an extended energy range.

6. General developments

ANSTO's research into COVID-19 has been fundamental to understanding of the virus. ANSTO opened up priority access on the beamlines at the Australian Synchrotron for researchers seeking to understand the virus and to develop potential treatments. To date, more than 120 COVID-19 experiments have been carried out at the Synchrotron. The access enabled researchers from Monash University to visualise the molecular structure of COVID-19 proteins, an important precursor to the development of potential treatments.