# AGENCY/DEPARTMENT: AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION

**TOPIC:** PETNET

**REFERENCE:** Question on Notice (Hansard, 19 October 2011, page 23)

QUESTION No.: SI-21

**Senator CAMERON:** Can you provide on notice what the benefits are to the community of PETNET in terms of the work that is being done and whether it is in the long-term benefit of ANSTO to continue this work with PETNET? **Dr Paterson:** We will do that.

#### ANSWER

#### **Direct Benefits**

The twin cyclotron and radiopharmaceutical production facility operated by PETNET Australia Pty Ltd, a wholly owned subsidiary of ANSTO, was opened in August 2009. Currently the Sydney based facility is primarily dedicated to producing fluoro-deoxyglucose (<sup>18</sup> FDG).

<sup>18</sup>FDG is a short-lived radio-isotope with a half-life of 110 minutes. When it decays it emits positrons which are the basis of imaging Positron Emission Tomography (PET). The radioisotope is chemically attached to deoxy-glucose molecule that is preferentially taken up by cancer cells allowing significant advances in staging and therapeutic follow-up of cancer. PET using <sup>18</sup>FDG is globally the fastest growing diagnostic imaging technique.

Currently PETNET provides critical cancer imaging capacity for nearly 6,700 patients in New South Wales (NSW) and an additional 1,500 patients in Queensland, South Australia, the Australian Capital Territory and New Zealand. PETNET provides critical diagnostic medicine to treat a range of cancers including lung cancer, gynecological cancers, lymphoma, brain cancers and cancers of the digestive system.

In recent years much of the <sup>18</sup>FDG used in PET applications in NSW was sourced from a commercial supplier in Melbourne and from a Sydney hospital which has its own cyclotrons to provide for its own needs. Hospitals in NSW have welcomed the establishment of PETNET as it provides security of supply. In a growing market, facilities like PETNET permit hospitals to establish and grow the national PET camera fleet which is essential for diagnostic outcomes in preference to investments in hospital based cyclotrons.

The fact that PETNET Australia Pty Ltd possesses two cyclotrons, which can back one another up, means that it can guarantee to provide a reliable supply of <sup>18</sup>FDG. PETNET is the only registered pharmaceutical supplier with an AustR number for <sup>18</sup>FDG and has received Good Manufacturing Practice approval by the Therapeutic Goods Administration. PETNET's product is the most rigorously tested and regulated <sup>18</sup>FDG in Australia.

### **Future Benefits**

Through the franchise and research arrangements in place with Siemens, ANSTO has access to novel radiopharmaceuticals in the development pipeline of Siemens. Recent discussions with Siemens have prioritised access to this developmental pipeline which can lead to the introduction of new PET radiopharmaceuticals to Australia without incurring the full developmental cost. The potential biomarkers for development are in the fields of oncology, cardiology and neurology. It should be recognised that bringing any new drug on the market involves a sequence of steps from chemical development, pharmacological profiling and toxicology studies through three levels of clinical trials enabling the completion of a new drug application, all of which is necessary to obtain the marketing authorisation. The success of this development is never guaranteed for every opportunity.

Through ANSTOs involvement on the Cooperative Research Centre (CRC) for Biomedical Imaging Development a further pipeline of PET radiopharmaceuticals is under development. This represents an opportunity for ANSTO and the commercial partners in the CRC to introduce new products, some of which could be contracted for production in PETNET as these opportunities mature. The operational experience of commercial manufacturing reduces the risk of over-optimistic "technology push" and increases the likelihood of sustainable outcomes with partners such as Cyclotek who established the first commercial PET operations in Australia. ANSTO LifeSciences, in partnership with researchers in Australia has a developmental pipeline which includes potential PET radiopharmaceuticals that could be developed commercially at PETNET in the future.

## **Collateral Benefits**

In the establishment of PETNET, ANSTO engineers, scientists and operations staff gained insight in key processes required for the proper and sustainable introduction of cyclotrons and radiopharmaceutical processing facilities in Australia – a capability that has national implications. The assimilation of these skills and competencies is currently being applied in four cyclotron projects at different stages of development in Australia. These projects will benefit from increased local content in the establishment phase and greater sustainability in the operational phase as a result of reduced dependence on foreign capabilities. This is crucial to the manufacture and supply of product into the clinical setting and in the establishment of dedicated research cyclotrons which will be the basis of future breakthrough in imaging, drug development and understanding the biochemistry and molecular biological pathways of disease.