AGENCY/DEPARTMENT: ANSTO

TOPIC: Pathways to exporting technetium-99m

REFERENCE: Question on Notice (Hansard, 31 May 2017, page 108-109)

QUESTION No.: BI-6

Senator LUDLAM: I know it is, and I know I am asking complicated questions. The NEA also said that their projected growth over the next couple of years was just 1.22 per cent annually, and that there are new molyproduction facilities planned in the next five years, at least that they have identified in Europe, North America, South America and the Far East. How much analysis have you done to ensure that you are not about to be competing in an oversupplied market? There are flat growth rates and a number of other big plants coming online. How do we know that we are not going to end up with a stranded asset as there is a glut?

Dr Paterson: We analyse all of the projects that are in view in the future. Most of the projects that are coming on stream at national levels are intended only to address national needs. Those non-reactor-based techniques have proven very difficult to make economic. A number of the other projects in the United States I think will eventually start to produce technetium 99m, but because they are going straight to technetium 99m, which has much shorter half-life, the scalability of those projects is quite difficult.

Senator LUDLAM: Because then it is harder to develop an export market with those? Dr Paterson: I think exporting technetium-99m directly is almost impossible. It is very difficult. We have looked and we continue to work on these models. We do model the accelerated performance to produce technetium-99m, for instance, in the Sydney setting. With the size of the city and the logistics that you require we do not think that Sydney could get away with just one facility producing technetium-99m.

Senator LUDLAM: Can you break it down for me? Your options are to produce moly-99, which is the precursor isotope with the longer half-life, so you can stick it in the fridge and fly it around the world—

Dr Paterson: Yes.

Senator LUDLAM: Or multiple particle accelerators salted around the place that do not use reactors, but that actually produce the technetium directly? Are those two pathways? Dr Paterson: There is possibly a third pathway, which is alternatives to the direct production of technetium-99m.

Senator LUDLAM: Could you provide us with some of them on notice? I am worried that I am testing the chairs patience. If there are other pathways there, could you provide us with those? Dr Paterson: Absolutely. We track these all the time. It is important, as an accelerator organisation as well—because we are not just a reactor organisation—that we can bring our knowledge of accelerator technology to bear on it.

ANSWER

Reactor-based technologies currently present the only reliable and efficient means of producing molybdenum-99 (Mo-99) or technetium-99m (Tc-99m), which are the parent and daughter isotopes that facilitate 85 percent of nuclear medicine procedures in Australia. Although it produces lower

yield than high enriched uranium based processes, the OECD Nuclear Energy Agency (NEA) and International Atomic Energy Agency (IAEA) regard the fully LEU-based production process that is used by ANSTO to be the gold standard of Mo-99/Tc-99m production, due to its proliferation resistance, easier availability of target material, and reduced security and safeguards burdens on transportation and processing.

Both the IAEA and the NEA have examined alternative technologies for the production of Mo-99 or Tc-99m and expressed strong doubts as to whether they could substitute for reactor-based technologies. There are two potentially technologically feasible methods for deriving Tc-99m using accelerators, however neither has been demonstrated to be economically or logistically viable, and neither are currently capable of producing Tc-99m at the quantity or quality required to ensure that Australian and international patients can reliably receive the nuclear medicine procedures that they require.

For more than a decade, researchers in Canada and elsewhere have been researching the direct production of Tc-99m using cyclotrons, but have not yet demonstrated this as a feasible method to satisfy clinical demand. Nor has the product they have manufactured met purity and quality assurance criteria mandated by health regulatory bodies such as Australia's Therapeutic Goods Administration or the US Food and Drug Administration. If direct production of Tc-99m were to prove feasible at some future date, it would require significant amounts of highly enriched molybdenum-100 (Mo-100) – which is a scarce and expensive commodity, the widespread use of which would impose significant costs on the health system. In addition, due to its rapid decay, Tc-99m cannot be transported sufficient distances to ensure supply for communities that do not operate cyclotrons locally. As a result, a very large number of cyclotrons, which have significant capital and operating costs, would be required to meet demand.

Another potential future alternative to the direct production of Tc-99m is the production of Mo-99 in advanced electron linear accelerator facilities. However, questions remain about whether the product would meet required activity and medical purity specifications. The electricity consumption of the required accelerator system would also be very high, which would be likely to result in costs of production much higher than for reactor-based production. In addition, this method involves the fissioning of uranium targets, meaning that the radioactive waste management challenges would be similar to those from reactor-based production.