CHAPTER FOUR

THE NEW RESEARCH REACTOR—MEDICAL ISOTOPES

Introduction

4.1 In considering the new reactor as a research tool, the Committee, in the previous chapter, touched on the production of radioisotopes, particularly for use in industry and environmental protection. It now turns its attention specifically to the use of isotopes in medicine. In this chapter, the Committee presents an overview of the adequacy of the supply and use of radioisotopes in diagnosis and therapy in Australia. It then considers the opportunities for using alternative sources of nuclear materials for medical applications including the use of alternative imaging modalities as a substitute for nuclear medicine procedures and the use of cyclotrons to produce non-reactor radioisotopes. The Committee looks at the importation of radioisotopes as a possible alternative to the domestic supply. Finally, it examines the importance of a national nuclear research facility in promoting research and development in Australian medicine.

4.2 Nuclear medicine first emerged after World War II when radioactive isotopes (radionuclides) became available. Since then the use of isotopes has expanded greatly. Today, radioisotopes are administered to a patient mainly to aid the diagnosis of illness or in a small number of cases for the treatment of disease including pain relief.

4.3 Although HIFAR was originally intended to provide irradiation facilities as a materials research reactor, shortly after its commissioning in 1960 the Government decided to supply radioisotopes from Lucas Heights.[1] By 1979 the radioisotope program had grown to 30 per cent of the total commitment of financial resources at Lucas Heights and was the largest single activity. Furthermore, projections at that time indicated that isotope demands from the nuclear medicine industry in particular, and industrial organisations generally, could increase significantly in the years ahead.[2]

4.4 The predictions were accurate. Medical radioisotopes have become an important component of Australia's health care system which depends on the economic and reliable supply of a wide range of isotopes for diagnosis and therapy. Indeed, nuclear medicine is one of the fastest growing fields in modern medicine and has been growing at some 14 per cent a year for the past five years.

4.5 In 1997, the Department of Health and Family services estimated that at this predicted growth rate about 1.5 million doses of nuclear medicine would be needed in

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1 Australian Atomic Energy Commission Research Establishment, *Review of Research Activities and Capacity and Proposals for the Future*, Report by the National Energy Research, Development and Demonstration Council, November 1979, p. A.5.2.1.

2 ibid, Chapter 5, p. 6 and Chapter 10, p. 2.

Australia in 2007. ANSTO claims that the new reactor, complemented by ANSTO's $20 million National Medical Cyclotron, is expected to go a significant way to meet this demand.[3]

The supply of radioisotopes in Australia

4.6 In announcing the Government's intention to replace HIFAR, the Minister for Science and Technology stated that the new reactor at Lucas Heights would 'build on Australia's life-saving medicine capabilities'. It is intended to maintain and improve health benefits provided to the Australian community by keeping the country virtually self-sufficient in nuclear medicines and also by promoting the development of new therapeutic and diagnostic substances.[4]

4.7 When a radioisotope is designed for use in a medical procedure, it is usual for it to be presented in such a way that it will target the part of the body being treated. It is then usually referred to as a radiopharmaceutical. ANSTO is the principal supplier of reactor based radiopharmaceuticals, or nuclear medicines, in Australia and is a significant exporter with approximately 13 per cent of total sales going overseas to destinations such as New Zealand and countries throughout Asia.[5] It is estimated that ANSTO produces 85 to 90 per cent of Australia's radiopharmaceuticals providing 100 per cent of iodine-131 and 90 per cent of technetium-99m.[6]

4.8 ANSTO produced more than 430,000 doses of nuclear medicine in 2000 and they claim that this number is expected to double in the next 5 years.[7] Of these 430,000 patient doses, about 350,000 are reactor-produced radiopharmaceuticals, mainly molybdenum-99 for generation of technetium-99m, and 80,000 are cyclotron-produced radiopharmaceuticals.[8]

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3 ANSTO, Press Release, 3 September 1997.

4 ANSTO 'Replacement Research Reactor for ANSTO', 3 September 1997, http://www.ppk.community.Australia/mediareleases.html (18 August 2000).

5 ANSTO home page http://www.ansto.gov.au/natfac/hifar.html (17 August 2000). ANSTO's annual report 1999–2000 states that export sales rose by 10 per cent in the last financial year to approach 13 per cent of total sales. It is unclear from the report, but it would seem that this figure includes the export of radioisotopes for both industrial, medical and research purposes. Export destinations are New Zealand, Malaysia, Indonesia, Singapore, Thailand, Taiwan, China, Hong Kong and Bangladesh.

6 Parliamentary Standing Committee on Public Works, *Proposed Replacement Nuclear Research Reactor, Lucas Heights, NSW*, Canberra, 12 August 1999, pp. 25–6.

7 ANSTO home page, 'HIFAR reaches 500th Operating program landmark', News Release, 28 August 1998, http://www.ansto.gov.au/infor/press/pr0898.html (17 August 2000) and http://www.usyd.edu.Australia/su/fasts/1997/Reactor.html (18 August 2000).

8 Parliamentary Standing Committee on Public Works, *Proposed Replacement Nuclear Research Reactor, Lucas Heights, NSW*, Canberra, 12 August 1999, p. 25.

Radioactive sources and nuclear medicines used in diagnosis and treatment

Diagnostic use

4.9 Radiopharmaceuticals for diagnosis currently dominate the use of medical isotopes. They provide the safest, most accurate and widely available means of diagnosing a range of medical conditions.[9] They are used in the detection and treatment of cancer, thyroid and heart disease.

4.10 Diagnostic applications in nuclear medicine comprise *in vivo* and *in vitro* methods. The *in vivo* involves the administration of a radiopharmaceutical to the patient and subsequent external detection with a gamma camera or some other detector. This procedure is non-invasive in nature and provides important information about organ functions and early detection of abnormalities. These diagnostic procedures support a broad span of medical specialities ranging from paediatrics to cardiology to psychiatry.[10] The *in vitro* applications involve the analysis of samples, often blood, taken from the patient.[11]

4.11 Technetium-99m is the most widely used nuclear medicine but, unlike many other commercial radioisotopes, has a relatively short half-life of about 6 hours.[12] Molybdenum-99 is the parent isotope and decays to form technetium-99m. To extend the shelf life of technetium-99m, it is provided to the market place in the form of molybdenum-99 generators. ANSTO began making these generators in 1967.

4.12 According to ANSTO, technetium-99m continues to hold a dominant place in nuclear medicine because of its 'outstanding versatility for general diagnostic purposes', especially in its capacity to detect a wide range of cancers and to investigate organ functions.[13] It can be formulated into a range of chemical compounds, enabling it to be targeted to different organs for diagnostic purposes. It is able to trace conditions and functions of the body without invasive and painful procedures.[14]

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9 Royal Australian and New Zealand College of Radiologists, submission no. 28.

10 IAEA Annual Report for 1999, http://www.iaea.org/worldatom/Documents/Anrep/Anrep99/, p. 7 (11 September 2000); Steffen Groth, 'Nuclear Applications in Health Care: Lasting Benefits', *IAEA Bulletin*, 42/1/2000.

11 Steffen Groth, 'Nuclear Applications in Health Care: Lasting Benefits', *IAEA Bulletin*, 42/1/2000.

12 Half-life is defined as the time in which one half of the atoms of a particular radioactive substance disintegrates into another nuclear form. Measured half-lives vary from millionths of a second to billions of years. Effective half-life is the time required for a radionuclide contained in a biological system, such as a human or an animal, to reduce its activity by one-half as a combined result of radioactive decay and biological elimination. 'Glossary of Nuclear Terms', http://www.nrc.gov/NRC/EDUCATE/GLOSSARY/glossary-fulltext.html (18 February 2001).

13 ANSTO home page, 'HIFAR reaches 500th operating program landmark', News Release, 28 August 1998, http://www.ansto.gov.au/infor/press/pr0898.html (17 August 2000).

14 Australian Atomic Energy Commission Research Establishment, *Review of Research Activities and Capacity and Proposals for the Future*, Report by the National Energy Research, Development and

4.13 As the application and range of technetium-99m labelled radiopharmaceuticals increases, the demand for this radioisotope is likely to continue to rise. ANSTO maintains that the present reactor is barely able to meet current demand for the parent isotope molybdenum-99. In the financial year 1999–2000, ANSTO reported continued strong growth of approximately 10 per cent in the sales of technetium-99m generators and iodine-131.[15] It expects that the planned new reactor would produce the volume and comprehensive range of diagnostic radiopharmaceuticals needed to satisfy Australia's requirements over the next 40 or 50 years.[16]

Therapeutic use

4.14 World-wide applications of nuclear related techniques for human health are expanding. One of the most important is the radiation therapy of cancer as a curative technique and for pain relief in cases that are incurable. Nuclear radiation is used in the destruction of unwanted or malfunctioning tissue in the body, such as cancerous tumours or an overactive thyroid. The ability of nuclear medicine procedures to target specific organs with the radiopharmaceutical means that a large dose of radiation may be delivered to the centre of the disease process while sparing the surrounding organs. According to the Australian New Zealand Society of Nuclear Medicine this is not possible in conventional radiotherapy where all organs within the target beam receive a radiation dose.[17]

4.15 According to Dr Michael Kitchener and the Royal Australian and New Zealand College of Radiologists, developments in nuclear medicine in Australia are in step with those overseas. Here, one of the increasingly important roles for nuclear medicine is in the field of therapy utilising reactor produced radioisotopes.[18] Professor Roger Uren, Royal Prince Alfred Hospital, Sydney, argues that the therapeutic use of radioisotopes is increasing as the effectiveness of such treatment is recognised and better methods of delivering the isotope to the tumour site are developed. Although the therapeutic use of reactor produced isotopes is relatively small, there are indications that this area will continue to be a major growth area for the treatment of

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Demonstration Council, November 1979, para. 5.2.2. See also Medical Isotopes, Sandia National Laboratories, http://www.sandia.gov/E&E/med_isotopes.htm (21 September 2000).

15 See ANSTO, *Annual Report 1999–2000*, p. 72.

16 ANSTO, Press Release, 3 September 1997; and ANSTO, Overview of Proposed Replacement Nuclear Research Reactor, http://ansto.gov.au/ansto/RRR/eis_overview.html (18 August 2000).

17 Its full title is the Australian New Zealand Society of Nuclear Medicine, Technologist Special Interest Group, (ANZSNMT SIG), submission no. 71. See also Dr Denis Gribbin who points out that nuclear medicine is an expanding speciality moving into exciting new areas of diagnosis and therapy. He spoke, for example, of molecules that seek out specific disease cell types and as a consequence, have the ability to deliver radiotherapy via radiopharmaceuticals to specific areas of disease, submission no. 35.

18 Dr Michael Kitchener, submission no. 21, p. 1; see also Royal Australian and New Zealand College of Radiologists, submission no. 28.

cancer.[19] For example thyroid cancer can be successfully treated with oral iodine-131 using a single capsule once a year. Iodine-131 is a reactor produced isotope as is samarium-153, used for palliative treatment of bone metastases in cancer patients.[20]

4.16 Indeed, Dr Nat Lenzo, a consultant general physician and nuclear physician at Royal Perth Hospital, noted that within the next few years it is envisaged that treatments, such as iodine-131 and yttrium-90 anti-CD20 for lymphoma, and yttrium-90 octreotide for neuroendocrine tumours, will become routine in clinical practice.[21]

4.17 Palliative treatments such as ^{153}SmEDTMP (Quadramet), recently granted pharmaceutical benefit status, are being used to relieve pain in patients with cancer.[22] Quadramet has also shown promise as a less systemically toxic agent to prepare patients with leukaemia for bone marrow transplantation.[23]

4.18 In summary the evidence presented to this Committee is that medical radioisotopes occupy and will continue to occupy an important place in Australia's health care system.

Alternative modalities to reactor produced radioisotopes for diagnosis

Computerised Tomography (CT), Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET)

4.19 As noted earlier, ANSTO meets most of Australia's growing demand for medical radioisotopes. A number of organisations and individuals, however, do not accept that Australia needs such products for medical diagnosis. They look to other diagnostic imaging modalities and assert that alternative technologies are now emerging which, in future years, could supplant modalities that rely on reactor produced radioisotopes.[24] Magnetic resonance imaging (MRI) and computer tomography (CT) are given as examples of technologies that could reduce the need for the use of medical isotopes produced in a reactor.[25]

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19 Dr Patrick Butler, submission no. 45; Professor Roger Uren, submission no. 12; Dr Christopher Rowe, submission no. 132; Dr Peter Robins, submission no. 94. See also Professor Barry Allen who pointed out to the Committee that the therapeutic uses of reactor produced isotopes accounted for only 3 per cent of patients receiving nuclear medicine studies at St George Hospital, Sydney. Information supplied to Committee by Professor Barry Allen, 29 January 2001.

20 Dr Fred Lovegrove, submission no. 15, p. 2.

21 Dr Nat Lenzo, submission no. 43.

22 See Dr Barry Chatterton, submission no. 41.

23 ANSTO, *Annual Report 1999–2000*, p. 72.

24 See for example, Dr Jim Green, *Committee Hansard*, 26 October 2000, p. 174. Parliamentary Standing Committee on Public Works, *Proposed Replacement Nuclear Research Reactor, Lucas Heights, NSW*, 12 August 1999, p. 26.

25 People for Nuclear Disarmament (NSW), submission no. 44; see also Mr Cameron Schraner, submission no. 56.

4.20 Physicians working in nuclear medicine do not share this view. They point to the increasing use of radioisotopes in nuclear medicine as evidence of continued growth and demand for services in this field of medical diagnosis.[26] For example, in the Department of Nuclear Medicine at the St George Hospital in Sydney, the workload has increased over 250 per cent since 1991 to 1999/2000 when over 6,000 patients underwent nuclear medicine studies. According to its Director, 'This progressive growth in Nuclear Medicine has parallelled and, at times exceeded, the growth in Ultrasound, CT scanning and MRI scanning and there is no indication that this continued expansion of Nuclear Medicine will cease'.[27]

4.21 The Australian New Zealand Society of Nuclear Medicine Technologists (ANZSNMT) also acknowledges the substantial advances made over the last twenty years in imaging modalities with CT scanning, ultrasound and MRI imaging being added to the arsenal of diagnostic imaging which previously relied on X-ray and nuclear medicine. It maintains, however, that despite the development of these various modalities, nuclear medicine continues to be widely utilised and maintains sustained growth rates. Based on their experience and pointing to the weight of evidence, nuclear medicine practitioners refute the suggestion that these alternative modalities will replace standard nuclear medicine techniques.[28]

4.22 According to nuclear medicine practitioners, nuclear medicine retains its place as an important modality in diagnosis because it offers particular advantages. It provides functional information about organs and tissues while other imaging modalities such as ultrasound, computerised tomography and magnetic resonance imaging are conceptually designed for anatomical or structural assessment. These other modalities supply a snapshot of the anatomy or structural information at the time of imaging without the functional component. In other words, they do not allow the biochemical and physiological functioning of the body to be observed directly and thus have not reduced the need for the functional information provided by radioactive scanning. For example, Mr Martin Carolan, a medical physicist, submitted that MRI has a limited ability to yield functional information which is not comparable to the detailed functional information available from the broad range of nuclear medicine scans that are routinely used.[29]

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26 ANZAPNM, submission no. 9, Senate Economics References Committee, p. 5; Professor Roger Uren, submission no. 12; Dr M. Blake, submission no. 22; Dr M. McCarthy, submission no. 23. Professor Uren submitted that 'studies using the tracer technique (nuclear medicine) are on the increase with new revelations in molecular biology and genetics'.

27 Dr Patrick Butler, submission no. 45.

28 Dr Michael Kitchener, submission no. 21, p. 1. See also Dr Mike Hayward, submission no. 26, p. 1 and comments by Dr Suresh Srivastava, Senior Scientist and Head of Radionuclide and Radiopharmaceutical Research Division, Brookhaven National Laboratory in Proceedings of the Conference on Medical Radionuclide Production using the Accelerator Production of Tritium Facility, 9–10 November, Augusta, 2nd edition revised March 1998, p. 31.

29 Mr Martin Carolan, submission no. 25, p. 1.

4.23 By and large, nuclear medicine practitioners acknowledge that in some cases there are alternatives to nuclear medicine examinations and cite the results of work being done with CT, MRI and ultrasound. But they assert that clinicians will use the best test for the job at hand and nuclear medicine provides unique information in a number of disease conditions. Dr Barry Chatterton, a physician in nuclear medicine, conceded that:

> Over the years, the 'market' has caused the extinction of once thriving nuclear techniques such as nuclear brain (blood brain barrier) and liver (colloid) scanning (superior methods for these indications such as brain CT and MRI were developed).

He made the point, however, that referring doctors will only use a technique if it helps to manage their patients and the choice may well be a procedure using reactor produced radioisotopes.[30]

4.24 Thus, although over time there have been significant developments in the various technologies used in the diagnosis of medical conditions, physicians note that the various imaging modalities are generally not competitive but complementary. They stress that diagnostic nuclear medicine is a modality which, because it provides unique functional information, works with ultrasound, CT scanning and MRI to provide a fuller picture of disease processes and thereby improve diagnostic and prognostic accuracy. Functional information obtained from nuclear medicine studies cannot replace structural or anatomical information obtained from other imaging modalities and vice versa. Drs Giovanni Bibbo and T. Cain submitted:

> …combined functional, anatomical and structural imaging is often performed in clinical practice to guide decision-making in patient management.[31]

4.25 According to Dr Barry Elison 'This multi-modality approach provides a more complete picture of disease process and thereby improves diagnostic and prognostic accuracy of studies.[32]

4.26 Another alternative imaging modality is Positron Emission Tomography (PET) which differs from CT scanning and MRI. It is a nuclear medicine technology which uses short lived radioisotopes to allow the non-invasive diagnostic imaging of metabolic processes in the living organism. Unlike reactor produced medical radioisotopes, isotopes used in PET are created in particle accelerators called cyclotrons. A cyclotron is an electrically powered machine that does not use uranium or produce the fission product wastes that are so difficult to dispose of.[33] As with

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30 Dr Barry Chatterton, submission no. 41.

31 Submission no. 49.

32 Dr Barry Elison, submission no. 64.

33 ANSTO Report, 'How the National Medical Cyclotron Works,' http://www.ansto.gov.Australia/information/reports/cyc.html (5 January 2001).

reactor produced isotopes, isotopes used in PET can be used to image and quantify biochemical and/or physiological function and hence detect functional changes.[34]

4.27 Those who suggest that PET presents a real alternative to procedures based on reactor produced isotopes emphasise that methods such as PET are much less expensive and less dangerous to humanity.

4.28 As with procedures using reactor produced medical radioisotopes, the application of PET is also growing. The first PET scan in Australia was performed in 1992 and was a brain scan on an epileptic patient. Over the years there has been a strong shift toward studies in oncology with over 80 per cent of PET examinations being performed in this field of medicine.[35]

4.29 According to a recent report by the Department of Health and Aged Care, developments in PET over the last decade include the widespread advent of scanners capable of whole body imaging and a dramatic increase in computer processing power allowing significantly improved image reconstruction and display.[36]

4.30 The radioisotope most commonly used in clinical PET is fluorine-18. Other radioisotopes associated with PET include oxygen-15, nitrogen-13 and carbon-11. These isotopes, however, have a very short half-life ranging from 120 seconds for oxygen-15 to 20.4 minutes for carbon-11. This short half-life limits their utility in clinical studies and requires that the PET scanner be co-located with the cyclotron that produces the radioisotopes.[37] Fluorine-18 has a half-life of 110 minutes, which makes it more practical for use in a clinical situation and allows it to be transported to sites remote from the point of production.[38] Nonetheless, the short half-life of this product does present some logistical difficulties.

4.31 In any case, PET still does not compete directly with nuclear medicine procedures. A Victorian report on PET services found that it was unlikely that they would replace other imaging modalities in the short term and that 'its application is a valuable adjunct to the existing suite of medical imaging services'.[39] Dr Christopher Rowe, Director of the Department of Nuclear Medicine and Centre for Positron Emission Tomography at the Austin & Repatriation Medical Centre, Melbourne, acknowledged that the use of cyclotron produced radioisotopes for PET scanning is increasing rapidly both internationally and nationally. He noted, however, that this procedure is not replacing established nuclear medicine investigations utilising reactor produced isotopes but rather reflects growth in a new area. He explained further:

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34 *Report of the Commonwealth Review of Positron Emission Tomography,* August 2000, p. 11.

35 ibid, pp. 5, 15.

36 ibid, p. 16.

37 ibid.

38 ibid.

39 ibid, p. 25.

> The role of the major traditional components of Nuclear Medicine remains undiminished. Tc-99m labelled tracers continue, and will continue to account for the vast majority of Nuclear Medicine studies in this Country. The short half-life and low radiation exposure from Tc-99m and its 24 hour a day availability from generators utilising reactor produced molybdenum-99, make it the ideal isotope for the majority of Nuclear Medicine investigations.[40]

4.32 Despite the development of non-reactor imaging agents, such as positron emitters, the evidence indicates that they will not replace current diagnostic agents such as technetium-99m and indium-111. The longer half-lives of current reactor produced isotopes have a physiologic and thus diagnostic advantage over the very short half-life isotopes used in PET.[41]

4.33 The weight of opinion among nuclear medicine practitioners indicates that the different methods of imaging work together—that reactor produced medical isotopes are a natural complement to other imaging techniques and none can substitute for the others.[42] Mr Martin Carolan submitted that often the other imaging modalities only serve to emphasise the relevance and accuracy of nuclear medicine studies. Thus, most working in this field believe that the exceptional and particular role of reactor based radiopharmaceuticals in diagnosis ensures that they will remain an important diagnostic tool for the foreseeable future.

4.34 While noting that the demand for alternative methods for imaging including CT, MRI and PET is likewise on the rise, the Committee is not convinced that these modalities can satisfactorily substitute for those relying on reactor produced medical isotopes. Rather than compete with one another, they are complementary diagnostic tools for various medical conditions. The Committee considers that in the future the application of medical radioisotopes for both diagnostic and therapeutic purposes will likely broaden as research continues into their use.

Substitutes for medical radioisotopes produced in nuclear reactors

Cyclotrons

4.35 While, accepting that medical radioisotopes will have a continuing and important role in medicine, some participants to this inquiry suggest that Australia turn away from the use of reactor produced radioisotopes. They propose that the country develop a reliance on cyclotron produced radioisotopes that can either replicate or mimic those created in a reactor.[43]

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40 Dr Christopher Rowe, submission no. 132.

41 See Dr Nat Lenzo, submission no. 43.

42 Mr Martin Carolan, submission no. 25, p. 1; Dr Mike Hayward, submission no. 26, p. 1; ANZSNMT SIG, submission no. 71; and Dr George Larcos, submission no. 9.

43 See Dr Jim Green, submission no. 1, Senate Economics References Committee, p.2.

4.36 Both reactors and cyclotrons are used to make radioactive isotopes and ANSTO uses both—its HIFAR reactor at Lucas Heights and the $20 million National Medical Cyclotron, which it owns and operates at Sydney's Royal Prince Alfred Hospital. It produces gallium-67, thallium-201, iodine-123 and fluorine-18 fluordeoxyglucose (FDG).[44] ANSTO states that around the world there are about the same number of reactors as cyclotrons producing medical radioisotopes as a major part of their functions but that 80 per cent of the radioisotopes actually used in medical procedures come from reactors.[45]

4.37 A cyclotron essentially comprises a pair of semicircular metal electrodes positioned between the poles of a large electromagnet. An ion source within the cyclotron generates charged particles, usually protons or duetrons, with a positive charge which are accelerated to a high velocity, directed onto a target, causing a nuclear reaction which ultimately alters the physical composition of the target material creating the desired isotope.[46]

4.38 ANSTO notes that there is a fundamental difference between the process used to create radioisotopes in a reactor and in a cyclotron which means 'as a general rule reactor radioisotopes will not be made by a cyclotron, nor will cyclotron radioisotopes be made in a reactor'.[47]

4.39 Mr Tony Wood, a retired ANSTO engineer, described the different processes. He explained that to produce isotopes in a cyclotron a narrow beam of charged particles is allowed to impinge on a tiny target. A reactor on the other hand provides a neutron field in a large volume and many targets can be irradiated at the same time simply by dunking them in this field. He asserted that the neutron deficient isotopes produced by cyclotrons supplement but do not substitute for the neutron enriched isotopes produced by reactors.[48]

4.40 Some witnesses dismiss this notion that isotopes produced in cyclotrons cannot adequately perform the functions of reactor produced radioisotopes. A number of participants to the inquiry assert that a cyclotron of sufficient power can produce just about any isotope—'Certainly any isotope that Australian hospitals and researchers might be interested in'.[49] Mr Bruce Taylor, from the University of New England Environment Group, expressed the views of a number of individuals and organisations when he asserted:

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44 ANSTO, *Annual Report 1999–2000*, p. 35.

45 National Medical Cyclotron, ANSTO homepage, http://www.ansto.gov.au/natfac/cyc.html (17 August 2000).

46 *Report of the Commonwealth Review of Positron Emission Tomography*, August 2000, p. 41; ANSTO Report, 'How the National Medical Cyclotron Works,' http://www.ansto.gov.au/ansto/information/reports/cyc.html (5 January 2001).

47 ANSTO homepage, http://www.ansto.gov.au/natfac/cyc.html (17 August 2000).

48 Mr Tony Woods, submission no. 11, p. 1.

49 Mr Cameron Schraner, submission no. 56.

> There are alternative methods for creating medical isotopes and new processes for different isotopes are being developed every day. The nuclear technology is unsafe and out of date.[50]

4.41 Nuclear medicine practitioners reject the proposition that cyclotron produced radioisotopes can substitute for reactor produced isotopes. Dr Fred Lovegrove submitted that iodine-131 is the main isotope used in the treatment of thyroid cancer, and is also used for benign thyroid disease. This isotope is also dependent upon a nuclear reactor, as is samarium-153, which is used for the treatment of painful cancer secondaries in bone for patients with breast and prostate cancer.[51]

4.42 The real test for cyclotrons, at this point of time, however, is whether they can produce technetium-99m. As noted earlier, the medical profession favour technetium-99m—a reactor produced isotope—as a diagnostic tool because of its physical and chemical characteristics. The gamma radiation emitted has the appropriate energy to provide a good image while the radiation burden for the patient is very low. Its half-life is six hours which is long enough for a medical examination but short enough for the patient to be able to leave hospital directly afterwards. Technetium-99m can be easily bonded to many different chemical materials and can therefore be used for a variety of diagnoses.[52] ANSTO maintains that it is the basis for more than 70 per cent of nuclear medicine procedures world wide so its central role in nuclear medicine cannot be disputed.[53]

4.43 Despite the widely held belief that radioisotopes, such as technetium-99m, can only be produced in a reactor, researchers in a number of countries continue to work on the possibility of using cyclotrons to produce this isotope. According to some witnesses, however, these researchers experience difficulties and their work has not yet produced the concrete results needed to attract substantial funding.[54]

4.44 The issue of whether technetium-99m can be produced in a cyclotron has been a contentious matter for many years. In 1993, cyclotron technology was evolving quickly, but the debate about whether technetium-99m could be produced successfully in these machines was unresolved. At that time, the McKinnon Review found that there were no cyclotrons producing this radioisotope and no plans anywhere to construct a large enough cyclotron for this purpose.[55]

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50 Mr Bruce Taylor, submission no. 14; Ms Sharon Davies, submission no. 84.

51 Dr Fred Lovegrove, submission no. 15.

52 Submission no. 9, Senate Economics References Committee, p. 5; Professor Roger Uren, submission no. 12; Dr M. Blake, submission no. 22; Dr M. McCarthy, submission no. 23.

53 ANSTO, *Annual Report 1999–2000*, p. 71.

54 ANSTO homepage, http://www.ansto.gov.au/natfac/cyc.html (17 August 2000). ANSTO states that 'as the operator of both a reactor and an accelerator for radioisotope production, ANSTO continuously monitors developments in both fields'. ANSTO homepage, http://www.ansto.gov.au/natfac/cyc.html (17 August 2000).

55 K.R. McKinnon et al, *Future Reaction: Report of the Research Reactor Review*, August 1993, p. xvii.

4.45 Five years on, the Draft Environmental Impact Statement for the RRRP found that in the intervening years there had been:

> no real advances towards the commercial production of technetium-99m using cyclotron technology and there has been little in the way of peer reviewed publications in this area. There is no cyclotron anywhere in the world that is producing commercial quantities of technetium-99m. There are also no current plans for realising such production.[56]

4.46 With few exceptions, medical specialists presenting evidence before the Senate Economics References Committee in 1998 believed that alternative technologies for the production of technetium-99m had not evolved in ways to indicate that they would be commercially available and reliable in the near future. They believed that their development so far did not warrant a reconsideration of the need for a new reactor.[57]

4.47 Professor Barry Allen was a notable exception to this general view. He told the Economics References Committee that he was currently using a spallation source at CERN in Geneva which allows the production of many exotic nuclides which can be used for the development of new cancer therapies and diagnostic techniques.[58] He acknowledged that this facility was very expensive, in the range of a billion dollars, but suggested that:

> …there are a number of accelerator possibilities and other types of research facilities which in total cost would be still a lot less than a research reactor, but which would impact on Australian science and technology to a much greater extent.[59]

4.48 The debate has made little progress since then. The nuclear medicine community continues to argue strongly that a research reactor is the only satisfactory means of meeting Australia's needs for medical radioisotopes. In opposition, a solid core of participants hold firmly to their position that given adequate funding and resources, researchers could develop a cyclotron capable of producing radioisotopes that would replace the need for reactor produced ones, such as technetium-99m.

4.49 Dr Garry Smith, Principal Environmental Scientist, and Manager, Environmental Science and Policy Unit, Sutherland Shire Council, asserted confidently that there is no question about whether technetium-99m can be produced

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56 PPK Environment & Infrastructure, *Replacement Nuclear Research Reactor: Draft Environmental Impact Statement*, Vol. 1/Main Report, July 1998, p. 6-10.

57 Submission no. 9, Senate Economics References Committee, Chapter Five.

58 Submission no. 4, Senate Economics References Committee.

59 Senate Economics References Committee, *Committee Hansard*, 16 April 1998, p. 99.

in a cyclotron. He maintains that 'it is proven, it is scientific and it is in the literature.'[60]

4.50 A number of participants supporting this contention cited an article by Dr Ralph Bennet et al. which appeared in *Nuclear Technology* to support their argument that there is a viable and better alternative to the production of technetium in a reactor. The article notes that an alternative source of technetium-99m would be well received if it were competitive in cost and if it avoided the environmental hazards and political liabilities of reactor based production. The authors of this paper argue that such a possibility exists and claim that the parent isotope molybdenum-99m can be produced in electron accelerators, which are far cheaper than reactors to build; can be located in several places close to patients; and do not rely on the nuclear fission of uranium.[61]

4.51 Mr Michael Priceman, Convenor of the Nuclear Study Group, Sutherland Shire Environment Centre, was clearly impressed by this study. He told the Committee:

> They claim that they can produce technetium-99 at one-third of the cost—with quality which is as good as the reactor based material, which is unsubsidised and which leaves no nuclear waste problem—needing a plant which cannot be used for weapons research. The cost of the individual units is about $A5 million. According to their figures, probably three units spread around Australia could supply our entire needs.[62]

4.52 Nuclear medicine practitioners dismiss these optimistic predictions. The Royal Australian and New Zealand College of Radiologists stated unequivocally that there was no clinically validated or commercially successful accelerator-based production of either molybdenum-99 or technetium-99m anywhere in the world.

4.53 Dr Kitchener, past president of the Australian and New Zealand Association of Physicians in Nuclear Medicine, endorsed these findings. He submitted that to his knowledge, despite the claims of new alternative sources of technetium-99m, there does not appear to have been any progress over the past 2 years to indicate there will be a commercially viable alternative in the foreseeable future.[63]

4.54 Dr Barry Chatterton also rejected outright the contention that cyclotrons are an alternative source of nuclear materials for medical applications. He agrees that while it may be theoretically possible to produce technetium-99m using accelerator technology, 'there has been no commercial (or even demonstration) implementations

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60 Dr Garry Smith, *Committee Hansard*, 25 October 2000, p. 70.

61 Ralph G. Bennett, Jerry D. Christian et al., 'A System of 99mTc Production Based on Distributed Electron Accelerators and Thermal Separation', *Nuclear Technology*, vol. 126, April 1999. See also Professor Richard Broinowski, submission no. 91.

62 Mr Michael Priceman, *Committee Hansard*, 25 October 2000, p. 118.

63 Dr Michael Kitchener, submission no. 21, p. 2.

of such technology on a clinical scale'.[64] Many of his colleagues restate this viewpoint.[65]

4.55 Dr Jerard Barry, the elected delegate, Community and Public Sector Union, Combined Nuclear Science and Technology Organisation Unions, maintains that his members at ANSTO constantly follow developments in the fields of alternative technologies, especially relating to the production of technetium. He believed that they have evaluated every nuclear scheme that has been proposed and on closer examination have found that the schemes were not viable.

4.56 In commenting specifically on the article in *Nuclear Technology*, his colleague, Dr Greg Storr, submitted that the project referred to was a research project, which studied, at the laboratory scale, the possibilities of using cyclotrons to produce technetium-99m. On further investigation, and after contacting the author of the article, Dr Bennett, he found that the research had been shelved because of lack of funding. To him this suggests that the project was a very difficult and very costly commercial prospect.[66]

4.57 Dr Clarence Hardy, President of the Australian Nuclear Association, came to the same conclusion. He argued that the experiments by Dr Bennett prove in principle that technetium can be produced on a research scale using this method. Nonetheless, he emphasises that millions of dollars would be involved in bringing this experiment to even a development scale, let alone a commercial scale.[67]

4.58 The Committee recognises that technetium-99m will remain the most important radioisotope for diagnostic nuclear medicine imaging for the foreseeable future.[68] It understands that the demand for technetium-99m labelled radiopharmaceuticals is increasing because the number of tests performed is on the rise and new radiopharmaceuticals being developed use the same radioactive isotope.

4.59 The Committee points to the state of current research which shows that while it may be technically possible to produce technetium-99m in a cyclotron, it is not commercially viable and that the possibilities of producing technetium-99m in a cyclotron has not progressed beyond the experimental stage. In summary, the

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64 Dr Barry Chatterton, submission no. 41.

65 Dr Allman submitted: 'The provision of routine medical imaging and radionuclide therapies is highly dependent on an adequate supply of medical radiopharmaceuticals which can only be produced in a reactor and not in a particle accelerator. The mainstay isotope in nuclear medicine is Tc-99m which is derived from reactor produced molybdenum'. See also Dr George Larcos, submission no. 9; Dr Fred Lovegrove, submission no. 15; Dr Barry Elison, submission no. 64; Dr Michael Kitchener, submission no. 21, Dr M. Blake, submission no. 22; Dr M. McCarthy, submission no. 23; Dr Patrick Butler, submission no. 45; Dr Christopher Rowe, submission no.132; Dr K. Lee, submission no. 83; Dr Stuart Carr on SBS, 'Insight', 10 August 2000.

66 Dr Jerard Barry and Dr Greg Storr, *Committee Hansard*, 25 October 2000, pp. 128–129.

67 Dr Clarence Hardy, *Committee Hansard*, 26 October 2000, p. 224.

68 Dr Christopher Rowe, submission no. 132.

Committee accepts that, at the moment, nuclear reactors will continue to be the only feasible source of neutrons for the manufacture of technetium-99m and that it is unlikely that anything will compete with the reactor produced molybdenum-technetium generator in the near future.

Importation of radioisotopes

4.60 With few exceptions, medical practitioners making submissions to this inquiry highlight their concern about maintaining a reliable supply of medical products and underline the need for an assured and readily available source of radionuclides. They draw attention to the importance of having a new reactor in Australia as the primary source for medical radioisotopes and point out that they rely heavily on the Lucas Heights reactor for the provision of diagnostic and therapeutic radiopharmaceuticals.

4.61 A number of witnesses place no such importance on having a domestic source of radioisotopes. They reject the argument that Australia needs a research reactor to obtain its supply of medical radioisotopes, suggesting rather that Australia secure its supply of radioisotopes from a combination of cyclotrons and/or overseas suppliers.[69]

4.62 In 1993, the McKinnon Review was not convinced of the viability of importation, especially when taking account of Australia's high standards in the delivery of nuclear medicine. Since that time, however, the international market has become more sophisticated and provides a reliable, more efficient and commercially viable source of radioisotopes. A number of countries, including the two leading world economies, Japan and the US, rely on imported radioisotopes to a large extent, but most particularly for technetium-99m.[70] With the production, supply and distribution of reactor radioisotopes now an established part of a global network and with no likely threat to world supplies, a number of participants had no qualms about urging Australia to develop a reliance on overseas sources in preference to a new reactor. [71]

4.63 Moreover, Dr Jim Green pointed out that 'if the reactor were shut down permanently, teething problems associated with importation would soon be overcome. In addition, long-term contracts for isotopes supply would be negotiated so there would be an additional cost advantage there'.[72]

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69 Catholics in Coalition for Justice and Peace, submission no. 2; Ms Amy Thom, submission no. 5; Mr Neil Macdonald, submission no. 10; Ms Christina Clark, submission no. 63; Waveney Kaeding, submission no. 66.

70 Senate Economics References Committee, *A New Reactor at Lucas Heights*, September 1999, para. 5.18. Dr Jim Green, submission no. 1, Senate Economics References Committee, p. 2.

71 See Mr J.R. Fredsall, submission no. 6, Senate Economics References Committee, p. 3. See also Professor Barry Allen, Radio National Transcripts, Background Briefing, 'Lucas Heights: Over Reaction?', 29 March 1999.

72 Dr Jim Green, *Committee Hansard*, 26 October 2000, p. 174.

4.64 Mallinckrodt, an international pharmaceutical company with over 30 years experience in importing pharmaceuticals into Australia, assured the Committee that it could supply the Australian market with molybdenum and a number of other radioisotopes out of its facilities in Petten in the Netherlands and Marylands in the United States.[73] In expressing confidence in its ability to supply the Australian market, it drew attention to its 'long and consistent history of shipping product and getting it there on time regardless of where it was in the world'. Mr Glen Pearce from Mallinckrodt explained that the company had been forced out of the Australian molybdenum market because of airline regulations of that time, shielding costs and lower competitive end pricing, especially from ARI.[74] He indicated that the company would be interested in reregistering to supply technetium generators to sections of the nuclear medicine community.[75] The question of market competitiveness as an impediment to the importation of radioisotopes to Australia then arises.

The market place and importation

4.65 A number of participants to the inquiry suggest that the cost of isotopes produced at Lucas Heights is much higher than that for the imported ones.[76] They assert, however, that the full costs of production are not built into the retail price of the local product—that in some way the products are subsidised. Subsidisation may, if it prices competitors such as Mallinckrodt out of the market, effectively close off the importation of radioisotopes as a viable option. Dr Garry Smith raised the following question:

> My concern and question is whether the heavily subsidised production of radiopharmaceuticals by ANSTO is anything more than a convenient supply at a very heavily subsidised price. If you admit it is very heavily subsidised, which I think it clearly is…then is it viable?…Why shouldn't it compete on the open market and why shouldn't the Australian taxpayer and the Australian consumer get the best possible price in competitive market rather than paying heavy subsidies for a reactor which gets a few radiopharmaceuticals?[77]

4.66 This matter of the subsidy is far from clear. Dr Jim Green maintains that determining the extent of subsidisation of isotopes produced at Lucas Heights is difficult because of the lack of information. According to Dr Green, ANSTO asserts

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73 Mr Todd Donaghy, *Committee Hansard*, 4 December 2000, p. 403.

74 Australian Radioisotopes (ARI), ANSTO's manufacturing arm.

75 Mr Glen Pearce, *Committee Hansard*, 4 December 2000, p. 402.

76 Mr Hans-Peter Schnelbögl, submission no. 82; Ms Jean McSorley, *Committee Hansard*, 25 October 2000, p. 49; Dr Garry Smith, *Committee Hansard*, 25 October 2000, pp. 66, 68; and Professor Richard Broinowski, *Committee Hansard*, 27 October 2000, p. 299.

77 Dr Garry Smith, *Committee Hansard*, 25 October 2000, p. 68.

that the relevant information is not publicly available because it is commercial-in-confidence.[78]

4.67 In reply, ANSTO states categorically that it does not 'routinely subsidise' Australian Radioisotopes' (ARI) arrangements.[79] It submitted that although the baseline operation of HIFAR is not charged to radiopharmaceutical operations, ARI's prices fully reflect ANSTO's marginal costs of production. The basic costs of having the reactor constructed, maintained, operating and regulated are part of the nation's price for meeting Australia's nuclear science and technology needs—the national interest— and therefore are not borne by the producers of the radiopharmaceuticals.

4.68 ANSTO explained that a nuclear research reactor operates continuously over lengthy periods and is capable of servicing many users at once. Because Lucas Heights is a multipurpose facility and also contributes to the national interest, ANSTO has adopted a particular costing regime to take account of these factors. It told the Committee that, for many years, the use of the reactor has been costed at an incremental rate, that is the full overhead recovery of the cost of extra fuel, labour and materials attributable to the particular irradiation or operation of the beam-line for the users.[80] According to ANSTO, this practice is common internationally for the operation of multipurpose neutron sources. It asserts further that the price charged to commercial users includes a component that represents a return on the use of the asset and that this may be significantly higher than the marginal cost.[81]

4.69 The Committee notes ANSTO's explanation in answer to the charge of subsidisation. Although ANSTO provided no breakdown of the exact costs involved in producing medical radioisotopes at Lucas Heights, the information made available does shed some light on the production costs and the reasons behind such a costing and pricing policy.

4.70 Nonetheless, because of the subjectivity and difficulty in analysing national interest and in assigning an economic value to it, the contribution made by the producers of radioisotopes to fixed costs seems to the Committee somewhat arbitrary. This flexibility would certainly allow ANSTO some latitude in pricing its radioisotopes. By failing to produce precise figures on its pricing regime, especially on the contribution paid by the producers of radioisotopes at Lucas Heights to fixed costs, the Committee believes that ANSTO leaves itself open to charges of exercising an unfair advantage in the market place.

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78 Dr Jim Green, submission no. 17B.

79 Australian Radioisotopes (ARI), ANSTO's manufacturing arm, is an independent commercial unit within ANSTO. Additional Information from ANSTO in response to questions on notice, 31 October 2000; ANSTO, 'About the National Medical Cyclotron', http://www.ansto.gov.au/natfac/cyc.html (17 August 2000).

80 ANSTO, submission no. 118A, p. 11.

81 ibid.

The logistics of importing radioisotopes

4.71 In turning to the logistics of importing short-lived radioisotopes, a number of participants to the inquiry note that ANSTO currently relies on imported radioisotopes during HIFAR shutdown periods. They insist that the adequacy of supply of radioactive sources and nuclear medicines has been proven again and again during these extended shut-down periods. They claim that isotopes are being imported without problems and the short-lived technetium-99m isotope is in any case supplied in generators[82] which extend the shelf life of the product to around a week.[83]

4.72 For example, the Anti-Nuclear Alliance of WA asserts most strongly that when HIFAR was shut down from February to May 2000 there was no dislocation in the supply of medical radioisotopes.[84] The Sutherland Shire Environment Centre also looked to the periods when HIFAR shuts down as proof that the importation of radioisotopes is an attractive option for Australia. It refutes claims by ANSTO that up to 30 per cent of imported radioisotopes arrive late or unusable and cites evidence given by the South African suppliers to Australia which indicates that over 98 per cent arrive on time.[85] They assert that during periods when HIFAR is shut down there is little interruption to the supply of radioisotopes.[86]

4.73 Finally, while conceding that there are a small number of radioisotopes with half-lives too short to allow for importation, Dr Jim Green argues that such isotopes are used infrequently, and alternative medical procedures are available to replace most or all of them.[87]

4.74 Medical practitioners who presented evidence to the Committee, however, tell a different story. Firstly, they refer to Australia's geographical isolation and feel strongly about the importance of having a local supply of radioisotopes and of not being dependent on multinational foreign owned companies.[88] The Chief Nuclear Medicine Technologist at the Canberra Hospital, in accord with the views held by many of his colleagues, particularly those in regional areas, informed the Committee:

> The current necessity of our department (and others providing a similar broad service) to purchase goods from overseas is unfortunate and mostly unavoidable. To propose that the daily isotope requirements of a clinical

82 Mr Hans-Peter Schnelbögl, submission no. 82; see also Mr Peter Reay, submission no. 133; Ms Sharon Davies, submission no. 84; A. Hindinger, submission no. 103.

83 Mr Glen Pearce, *Committee Hansard*, 4 December 2000, p. 402.

84 The Anti-Nuclear Alliance of WA, submission no. 36. See also Community Anti-Nuclear Network of WA, submission no. 130.

85 Sutherland Shire Environment Centre, submission no. 121.

86 People for Nuclear Disarmament, submission no. 138.

87 Senate Economics References Committee, *A New Reactor at Lucas Heights*, September 1999, para. 5.22.

88 See, for example, Dr Denis Gribbin, submission no. 35. See also Dr D. Neil Jones, submission no. 13; Dr Barry Chatterton, submission no. 41; Dr Barry Elison, submission no. 64.

> department may be met only from overseas suppliers is ludicrous. The reactor-produced isotopes at Lucas Heights are critical in meeting the national requirements of a market that seeks urgency and immediacy. Its ongoing future must be considered as crucial in producing the vast majority of Nuclear Medicine isotope needs for the foreseeable future.[89]

4.75 Doctors identified a number of logistical problems which they found caused serious disruption to supplies. For example, Professor Roger Uren maintained that:

> A reliable local supply of these reactor isotopes such as 99mTc and I-131 is vital for the health of Australians. To consider a shift to the importation of such tracers is to court disaster. A snow storm in Toronto could easily lead to a life saving tracer being unavailable here in Australia.[90]

4.76 Dr Hugh Dixson, who has direct experience of importing molybdenum-99 generators from Europe, underlined this view. He found the overseas supply of generators unreliable and recounted that at any point along the airfreight route an individual pilot could decide that he or she did not want to carry radioactive cargo. He submitted:

> Every month or so our generator would be off-loaded in Singapore (for example) on the pilot's whim and there would be a 2–3 day delay during which our work would be disrupted. It was only because we could source locally produced Tc99m that we were not more significantly affected.

For this reason, he now uses a locally produced generator.[91]

4.77 In summary, the main concern with the importation of medical radioisotopes is the possibility of delay or interruption to supply. This is particularly so with short lived therapeutic isotopes. In these cases local supply becomes important as high specific activities are required for optimal clinical use.[92] A local supply also ensures maximum flexibility in meeting patients' needs.[93]

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89 Information supplied to the Committee by Mr Chris McLaren, Chief Nuclear Medicine Technologist, the Canberra Hospital, 31 October 2000. This information was supplied in response to evidence given by Professor Broinowski who, using the Nuclear Medicine Department of the Canberra General Hospital as a guide to general Australian practice, suggested that ANSTO's claims are exaggerated and misleading. He maintained that the Canberra Hospital does purchase radioisotopes on a regular basis from ANSTO including molybdenum generators but that the hospital has no special preference for supplies from Lucas Heights and is certainly not dependent on them. He had been led to believe that the hospital routinely purchases these products from commercial sources such as Amersham and Mallinckrodt. Professor Richard Broinowski, submission no. 91.

90 Professor Roger Uren, submission no. 12.

91 Dr Hugh Dixson, submission no. 77. See also Dr Denis Gribbin, submission no. 35 and Professor Roger Uren, submission no. 12.

92 Dr Peter Robins, submission no. 94. Likewise, Professor Garnett argued that the new and emerging isotopes, 'the therapeutics, those that are being used for treatment and for palliative care, have got very short half life, a matter of hours, and we can't import those from overseas. So if Australia is to have this

4.78 While practitioners agree that they manage when HIFAR is shut-down, they stress that the importation of radionuclides is a safety net and not a workable long term option.[94] They draw attention to the time taken for the transport of radioisotopes from Sydney to the other capital cities and the even longer delay when further transport is required to country centres. They claim that transport from overseas only heightens their concern.[95]

4.79 For example, Dr Bibbo and Dr Cain maintain that when HIFAR is shut down it is possible to put in place strategies to cope with overseas supplied technetium-99m generators. Such measures include scheduling lighter workloads to reduce demand for radiopharmaceuticals, cancelling and rescheduling studies until reactor radionuclides are available. They argue that in the long run this practice cannot be sustained without compromising patient care.[96] Dr Lee, Director, Department of Nuclear Medicine and Ultrasound, Bankstown-Lidcombe Hospital, strongly supports this view. He explained that during the shut down of the reactor careful planning meant that the needs of the country were met. Nonetheless, he points out that many departments were restricted and could not deliver the usual level of service.[97]

4.80 In summary, the nuclear medicine practitioners who made submissions to this inquiry argue that the use of reactor based radiopharmaceuticals in Australia continues to grow and that the new reactor will provide the extra capacity to meet this demand. They do not believe that the demand could be met satisfactorily from imports which, they maintain, are subject to disruption.

4.81 The Committee listened to the argument that there now exists an efficient and reliable global supply and distribution network that could supply Australia with most of its medical radioisotopes, including technetium-99m in the form of molybdenum generators. It also notes the claims that there are logistical problems in importing radioisotopes and appreciates the standpoint of nuclear medicine practitioners in underlining the importance for Australia to be self-sufficient in this area.

4.82 The Committee is not convinced, however, that these difficulties constitute a serious obstacle to the successful importation of radioisotopes. For instance claims about potential transportation delays are equally applicable to the distribution of radioisotopes within Australia as noted in Paragraph 4.78. Currently the only supply of technetium-99m comes from Lucas Heights and the generators have to be transported extensive distances from Sydney to other parts of Australia as well as

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first-world medical capability, we need a facility here in this country'. Transcript, 'Lateline', 10 June 1997.

93 Dr D. Neil Jones, submission no. 13.

94 For example, see Dr Barry Chatterton, submission no. 41.

95 See ANZSNMT SIG, submission no. 71.

96 Drs Giovanni Bibbo and T. Cain, submission no. 49; see also Dr K. Lee, submission no. 83.

97 Dr K. Lee, submission no. 83.

exported to other countries in the region. The Committee does not accept that relying on imports would exacerbate these problems. Indeed, international links into airports in cities other than Sydney (eg Perth, Brisbane) might provide a quicker supply.

4.83 The Committee believes that importing companies have not had the time or opportunity to establish their credentials in this area and that, should the need arise, they may well prove a satisfactory alternative to the local supply of radioisotopes.

Medical research and development

4.84 Overall, those practising nuclear medicine state firmly that if the nuclear reactor were to close and Australia relied on the importation of radiopharmaceuticals to meet its demand, the range and number of nuclear medicine tests available for clinicians would be limited and its reliability of supply would be adversely affected. But they are also particularly concerned that teaching, research and the development of new nuclear medicine agents would be severely hampered, with wide ranging implications.[98]

4.85 This argument in favour of Australia having a national facility runs the same course as the discussion in the previous chapter about suitcase science and the role of a local facility in promoting and developing research in Australia.

4.86 According to the Australian New Zealand Society of Nuclear Medicine, scientists are constantly searching for and finding new, better, more efficient and more effective ways to utilise radioisotopes for human benefit.[99] For example, SIRTeX Medical Limited, a listed Australian public company, informed the Committee that with the collaboration of the Cancer Research Institute they had produced radioactive yttrium microspheres. These products are implanted into patients with primary and secondary liver cancer and, according to SIRTeX, represent a significant breakthrough in the treatment of this usually fatal disease.[100] It submitted that HIFAR is essential for the neutron bombardment of the yttrium, which has a 64-hour half-life, to convert it into a radioactive therapeutic source.[101] Put succinctly, Australia 'needs more of such successful therapies not less'.[102]

4.87 Furthermore, ANSTO does not simply produce medical radioisotopes; it also participates in medical research and development associated with nuclear medicine. Dr Colin Styles, Director, Barwon Medical Imaging, Geelong Hospital submitted that

98 Dr George Larcos, submission no. 9.

99 ANZSNM SIG, submission no. 71.

100 SIRTeX Medical Ltd, submission no. 24, p. 1.

101 ibid.

102 Professor Roger Uren, submission no. 12. See also Dr Patrick Butler, submission no. 45.

the isotope production at Lucas Heights provides a core of experienced scientists who provide training and education to the medical community.[103]

4.88 ANSTO informed the Committee that its Radiopharmaceuticals Division is actively involved in the discovery of new sophisticated radiopharmaceuticals. It submitted:

> The major thrust of current research is looking into markers indicating the growth of malignant melanoma. We are currently doing this using tracers such as iodine-123, fluorine-18, or copper-64. If the clinical results of those trials are positive, we will explore ways of finding a technetium label for the marker. There is a real possibility of a new, Australian invented, radiopharmaceutical emerging in the foreseeable future.[104]

4.89 Indeed, in light of the advances made in the use of radioisotopes and its wide and growing use in the diagnosis and treatment of cancer, health care workers suggest that Australia should be looking for opportunities to increase the range and quality of medical isotopes that it can produce.[105] A number of nuclear medicine physicians agree that for Australia to remain at the forefront of these new developments, it must have its own nuclear reactor with the nuclear physics and nuclear chemistry infrastructure that stems from this.[106]

4.90 The issue about research funding and the possibility of closing off options was taken up in the previous chapter in the discussion about spallation sources as an alternative source of neutrons for research. This question about priorities in funding is also relevant to the debate about supporting a local research reactor as a source of medical radioisotopes and as part of Australia's medical research infrastructure.

4.91 Some participants to the inquiry argue that, in continuing to direct funds into reactor produced isotopes, the incentive and resources to develop alternative methods are undermined.

4.92 Dr Jim Green in his submission to the Senate Economics References Committee suggested that a study be undertaken into the costs and benefits of short to medium-term investment in non-reactor radioisotope sources. In particular, he advocated the systematic pursuit of research into cyclotron and spallation technology, with the longer-term aim of complete or near-complete reliance on domestic cyclotrons and/or spallation sources.[107] Put simply, Dr Green wanted to 'close the reactor and invest in alternative technologies'.[108]

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103 Dr Colin Styles, submission no. 65.

104 ANSTO, supplementary submission no. 118A, p. 13.

105 Mr Martin Carolan, submission no. 25, p. 2.

106 See, for example, Dr Denis Gribbin, submission no. 35.

107 Dr Jim Green, submission no. 1, Senate Economics References Committee, p. 2.

108 Dr Jim Green, *Committee Hansard*, 26 October 2000, p. 172.

4.93 This Committee received similar advice from Professor Barry Allen, Director, Centre for Experimental Radiation Oncology, Sydney who argued that a major problem with the nuclear medicine profession is that they provide no overview as to the future of nuclear medicine in Australia and thus give little guidance for government to fund its development and operation. He asserted:

> No one has examined the comparative value or cost-effectiveness of the proposed reactor compared with other major facilities in nuclear medicine and Science…The question is not whether the proposed reactor would be valuable. Of course it will be, it will be a major asset for neutron beam physics and a resource for NM [nuclear medicine]. However, the cost effectiveness cannot be justified unless a detailed analysis is made of other major R&D facilities needed in Australia.[109]

4.94 In particular, he informed the Committee that the submissions from nuclear medicine physicians do not acknowledge the developing role of accelerator produced alpha sources for therapy. According to the Professor, while such sources have the potential to inhibit early stage secondary disease, they are only now going into clinical trial. He notes that there is no funding allocated to support the accelerator production of actinium-225 which holds promise for the treatment of cancer. He urges physicians to take a more forward-looking assessment of nuclear medicine.[110]

4.95 His views are supported by Dr Susan Wareham, President of the Medical Association for Prevention of War (Australia), who also noted the lack of funding into the potential of cyclotrons to produce most of Australia's radiopharmaceuticals. She maintained that:

> …a reactor should not be seen as the only way in which cancers can be treated. For example, alpha emitting therapies have also not had the research funding that is needed, and they offer some promising cancer treatments.[111]

Dr Wareham concluded that given the significant concerns about the reactor, the justification for the reactor on medical grounds is not well established considering 'that research into alternatives has not been carried out'.[112]

4.96 The Committee acknowledges the importance of Australia remaining involved in medical research and development. It notes that nuclear medicine is but one branch of a much broader discipline and that medical research in Australia covers many areas. The Committee understands the view that the proposed new research reactor would provide valuable research opportunities for medical scientists.

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109 Professor Barry Allen, Information supplied to the Committee, 29 January 2001.

110 ibid.

111 Dr Susan Wareham, *Committee Hansard*, 27 October 2000, p. 269.

112 ibid, p. 268.

4.97 However, the Committee also accepts the submission of people such as Professor Allen that a comparative analysis has not taken place to ascertain whether the proposed new research reactor is the best possible investment in Australian medicine. This project will involve expenditure of at least $300 million plus ongoing costs for at least the next forty years. There is no doubt that many other areas of medical research and development that could benefit from even a small proportion of that expenditure.

4.98 The Committee again expresses its disappointment that a full public inquiry was not held before the decision to build the new reactor was taken. Such an inquiry would have allowed medical practitioners and researchers to build up a comprehensive picture of Australia's future health needs and the most beneficial areas of research. With this information, Government would have been better placed to make an informed judgement on setting priorities in funding research into Australian medical science.

4.99 The lack of consensus about key issues is a concern given the size of this single investment. In particular there is a need for a full technical review to determine whether:

- **cyclotrons could at much lower cost provide for a substantial part of the Australian market for nuclear medicines;**

- **a secure arrangement could be made to import molybdenum-99 for the generation of technetium-99m within Australia, as is the case in most other major countries; and**

- **whether other low volume products that cannot be made in a cyclotron could be imported and the medical implications if they are temporarily unavailable.**

4.100 The Committee further notes that even accepting the argument that it would be preferable for Australia to be self sufficient in nuclear medicines it has not been demonstrated that the proposed new 20 megawatt reactor on the Lucas Heights site is the most effective, economic and environmentally appropriate way of achieving that goal.