

Collaborative Procurement of a Clinical Modality

a report by

Roy Aitken

*Manager, Area Facilities Development, North Metropolitan Health Service (NMHS),
Department of Health, Western Australia*



Roy Aitken is Manager of Area Facilities Development for the North Metropolitan Health Service in Perth, Western Australia. He is also a Fellow of the Institute of Hospital Engineering, Australia, having been a member for 24 years. He has written and published many health engineering management papers in that time. Mr Aitken has 28 years' experience in health engineering in both the private and public sectors in Australia and England and has worked in a range of operational, development and consulting roles.

It is often observed that facilities management is not involved at an early enough stage in project procurement.

Procurement of the first positron emission tomography (PET) camera and associated cyclotron for the Western Australia (WA) PET Centre at Sir Charles Gairdner Hospital, Perth, WA, has been undertaken with comprehensive collaboration and communication between all stakeholders.

The benefits of this collaborative approach will be demonstrated throughout this article, illustrating the complexity of the technology and highlighting the need to comply with a broad number of regulatory authorities and stakeholders whilst co-ordinating the building works with the supply of equipment from the US and several European countries.

Defining PET

PET is a non-invasive, diagnostic imaging technique for measuring the metabolic activity of cells in the human body. It is useful clinically in patients with certain conditions affecting the brain and the heart, as well as in patients with tumours and metastases. The field of PET has been emerging into clinical diagnostic medicine and is approved by many insurance carriers for coverage.

In PET, a 'tagged' substance is injected or inhaled. This moves normally through the patient to accumulate in the targeted organ. The patient is scanned using a PET camera that translates data into computer images. Malfunctions in metabolism are immediately apparent by abnormal distribution of the tagged substance.

PET shows blood flow by imaging trace amounts of radio-isotopes. It identifies decreases in blood flow to, say, parts of the brain, indicating such diseases as Alzheimer's disease.

One of the main differences between PET and traditional nuclear medicine techniques is the use of these very short-lived radio-isotopes that are best produced by an on-site cyclotron.

The cyclotron accelerates protons to very high energies. It is similar to the linear accelerator used in radiation oncology, except that linear accelerators accelerate electrons. The accelerated protons are directed onto a target, producing the required radio-isotope that is then transferred automatically to the adjacent radiopharmaceutical laboratory, where it is synthesised into a radiopharmaceutical suitable for injection into patients.

Location

Early discussions involved representatives from all metropolitan teaching hospitals, and the location of the most appropriate site was identified as Sir Charles Gairdner Hospital (SCGH), located 5km from the centre of Perth at the Queen Elizabeth II Medical Centre.

The main determinant in this decision was the impressive vision of the individuals in the departments of nuclear medicine, medical physics and radiation safety in convincing the original designers of the mid-1970s building to incorporate a basement bunker for a PET cyclotron. The roof of this bunker was the 1,200mm floor of the PET camera room at the first floor level in the nuclear medicine department.

SCGH is the state referral centre for a number of specialist and super-specialist services, including elective neurosurgery, complex radiotherapy, exotic infections, adult liver transplantation, tuberculosis and Hansen's disease. It is also recognised as a major state centre for other specialties. These include:

- cardiac catheterisation and cardiac surgery;
- cancer treatment;
- respiratory medicine;
- bone densitometry and metabolic bone disease;
- massive bone allografting;
- complex upper gastrointestinal endoscopy;
- pulmonary physiology;
- sleep disorders of breathing;
- pain management;
- interventional radiology;
- intraocular surgery;

- microvascular surgery;
- liver disease; and
- renal disease.

It is the principal medical teaching hospital for the Medical School of the University of Western Australia and also has very close relations with Curtin University (nursing, allied health professions and medical laboratory sciences) and Edith Cowan University (nursing).

Business Case

The WA PET Centre is jointly funded by the state and federal governments as part of a three-year trial involving seven PET centres across Australia. The Federal Department of Health and Aged Care will pay the cost of PET scans for designated clinical indications through the Medical Benefits Scheme. It is expected that, following an evaluation of the usefulness of PET during this initial period, a broader range of indications will be included.

Early justification of the costs of establishing such a centre revolved around the success rate of early diagnosis and the prevention of surgery intervention and the adverse effects of sending patients to PET facilities in the eastern states. In a significant number of patients (up to 40% in some studies), management would be changed as a result of the PET investigation, i.e. unnecessary surgery would be withheld.

Subsequent data in December 2002 reported that 214 Western Australian patients referred for PET scans had been flown to the eastern states in the previous 12 months. Of these, 177 required a carer to accompany them on the journey. The cost to the public health system was about A\$2,368 per patient (total cost over 12 months for patients and carers was A\$506,930).

A quantity surveyor was engaged to prepare an estimate of the building costs for inclusion in the business case. Considerable input from engineering staff relating to electrical and chilled water availability was factored into these estimates in July 2001. The estimated total commitment for building works, including fees, was A\$1,639,000. Net present value calculations were also carried out on various options at this stage.

In December 2001, SCGH was awarded the contract to set up a PET facility.

Planning

Parallel to the business case drafting, preliminary planning was undertaken on both the PET camera

Table 1: Facility Planning Checklist

Discipline	Input required?		Actioned (contact name)
	Yes	No	
Client	✓		
Corporate/Executive Sponsor			
Engineering and Building Services	✓		
Supply Chain 2			
Fire and Safety			
Emergency Procedures Project Officer			
Infection Control Unit			
Medical Technology and Physics			
Biomedical Engineering			
Radiation Protection			
Information Technology			
Regulatory and/or Statutory Authorities (Identify)			
Clinical			
Security			
Occupational Health			
Disability Services			
Communications			
Patient Support Services			
Corporate: Information Services			
Medical Services			
Nursing Services			
Finance and Corporate Information Services			
Unions			
Public Relations			
Others (Identify)			

suite and the cyclotron bunker area. The medical technology and physics and nuclear medicine departments were also drafting procurement plans for their respective equipment that would be procured through the State Health Supply Council process.

During the winter season, a decision was taken to carry out some early forward works by cutting in chilled water isolating valves to the 450mm-diameter flow and return lines during a major shutdown of this site service. This provided the necessary take-off point for the supply to the cyclotron heat exchanger.

SCGH has utilised a process mapping software package to identify work flow processes prior to schematic design on several major capital projects. This greatly assists all stakeholders in viewing the process on paper and fine-tuning any anomaly in the process. In this case, the flow of the radiopharmaceutical product from the GMP laboratory to the patient was crucial in the layout of both the laboratory and the patient preparation area.

A stakeholder checklist (see Table 1) is also utilised to ensure that all relevant stakeholders are made aware of the proposed plans and their impact on the service and have the opportunity to comment

on the design solution, for example IT and communications services.

All capital works projects are procured through the State Government Department of Housing and Works. A brief was issued for lead consultant architects to submit proposals for the combined PET camera suite and the cyclotron bunker/Good Manufacturing Practice (GMP) laboratory facility. On engagement of the lead consultant, all sub-consultancy disciplines were also engaged on a competitive quotation basis.

The design team then embarked on the design/documentation phase using the outcomes from the process mapping exercise and other preliminary planning work.

The design team had to make some assumptions at this early stage as no decision on the outcome of the type and make of camera, cyclotron and hot cells was yet available.

The procurement phase for the equipment advanced to a contract award status in July 2002. A decision was made through an Australian agent to purchase a Phillips Allegro PET camera (US), IBA cyclotron (Belgium) and Comecer Hot Cell equipment (Italy). There was also a range of equipment from other sources. The other interesting procurement process was obtaining the raw material for the radiopharmaceuticals and heavy water. Again, a competitive process was undertaken and the heavy water procured from Israel.

When the delivery dates of all this equipment were known, it became apparent that a PET camera could be installed earlier than the supporting cyclotron/hot cells.

The Federal Department of Health and Aged Care contract required the PET camera to be operational by December 2001. Although it is optimal that fluorodeoxyglucose (FDG) be produced on the site of the camera, another competitive quotation process was issued to procure FDG for the period between the commissioning of the camera and the commissioning of the cyclotron and GMP laboratory. The main drawback was the need to provide several times the required amount to satisfy requirements to scan three or four patients due to the very short two-hour half-life of the product. Nevertheless, it was decided to proceed on this basis, which meant splitting the design/documentation phase into two separate building contracts.

Design/Documentation

The design of the Stage 1 PET camera suite was reasonably straightforward, with the exception of

some detailed shielding of the camera room and advance work for the service elevator in Stage 2 works.

The shielding comprised two 'skins' of solid concrete Besser blocks. The brick coursing was offset both horizontally and vertically to reduce any potential radiation penetration. Lead sheet of 15mm was used in a small plumbing duct and a lead-filled door installed to the room. No shielding was required for the slab above, as the physicists' calculations determined that there was adequate density and distance to obviate this need.

The orientation of the camera was critical as plans for a computed tomography (CT)/PET upgrade was also considered, as well as the use of ¹⁵O (oxygen) that will require a very specialised ventilation installation. A 3mm outside diameter stainless steel line was installed from the camera to the cyclotron bunker for this future requirement.

The design of the Stage 2 cyclotron bunker and the GMP laboratory relied very much on the briefing and calculations of the physicists and radiochemist. Although a bunker existed with removable panels, there was a considerable amount of concrete shielding required to create an entry maze and thickening of existing walls. The method of inserting the 26-tonne cyclotron also required consideration. The route and method of installing 3.5-tonne hot cells also required careful planning. The transfer of the product from the cyclotron to the laboratories required the installation of shielded trenches.

Factored into all this design work was the requirement for the interface of the cyclotron to the hot cells and interlocks to the building management system. A programmable logic controller (PLC) was supplied that accepted all interface inputs from the cyclotron control panels and the hot cell control panel. This proved to require on-going liaison and changes progressively through to commissioning. The interpretation of language terminology added another dimension to this aspect of the project.

Construction

On September 2002, a building contract was awarded for the construction of the PET camera suite. Care was taken to ensure that no construction/demolition materials or dust was transmitted to adjacent nuclear medicine facilities by constructing dust-proof slab-to-slab partitions. The work was completed on schedule, the camera installed and commissioned and the first patient scanned in November 2002.

Testing carried out by the physicists demonstrated that their calculations for the required shielding was proven adequate, as required by the Radiation Safety Council. All air-conditioning, medical gases and electrical works were commissioned and all results incorporated in the operating manuals and 'as constructed' record now held in the engineering and building services technical library and drawing office.

The design of the bunker and laboratory area presented some special design conditions.

The GMP laboratory was required to operate at 18°C with high-efficiency particulate air (HEPA) filtered full fresh air. All exhaust from the hot cells was directed to a radioactive exhaust system re-utilised from a previously unused fume cupboard and discharged at the roof level of the 10-level podium building. Fire protection was via a very early smoke detection alarm (VESDA) monitoring system and dry-charged sprinkler system. The rooms' walls and ceilings were manufactured from coolroom panels with a coved sheet vinyl floor. There was a 45Pa differential pressure gradient required between the GMP/quality control laboratories, anteroom and outer anteroom to the general laboratory. The doors between the anterooms and the general laboratory were interlocked in order that one door needed to be closed before the other could be opened.

The radiochemist briefed the design team on the special requirements of the finishes for the GMP laboratory, as required by the Therapeutics Goods Administration. All joints, screw heads and pop-rivet heads were required to be sealed with an antifungal silastic.

In the cyclotron bunker, smoke detectors were the only mode of fire detection installed. It has yet to be determined whether neutron bombardment will have any effect on these detectors. General lighting and tempering air-conditioning were the only other building services. All special gases (16) were installed by the cyclotron supplier. The cyclotron control room was constructed with a built-up computer floor, as required by the manufacturer. Penetrations of 100mm diameter were drilled through the 1,200mm-thick bunker wall at low level to provide access for all cyclotron radiofrequency and control cables and gas lines.

Chilled water was provided to the cyclotron heat exchanger at a preset rate and temperature. The circulating cooling water for the cyclotron was reverse osmosis quality water from the hospital's central supply fed to a header tank on the heat exchanger.

A special boronated plastic door 200mm thick was installed at the entry to the bunker maze as the last

safeguard from stray neutrons. The air-conditioning supply duct in the bunker was also offset to reduce any chance of neutron penetration. The 3mm-diameter stainless steel ¹⁵O delivery line to the PET camera directly above was also offset.

All tender drawings for each stage were submitted to the Radiation Safety Council for approval and any recommendations for design changes. At both stages, minor modifications to the design were incorporated.

The Stage 2 cyclotron and GMP laboratory building works commenced on 13 January 2003, but the building programme for this stage had several milestones. Shipping details for the cyclotron and hot cells still had not been clarified and were critical to the construction programme. The cyclotron needed to be inserted prior to closing off the bunker and hot cells needed to be installed before the GMP laboratory ceilings could be completed.

SCGH had undertaken the demolition of the internal building structure, so the builder had vacant possession of the site.

As the cyclotron was to be inserted at the finished floor level of the bunker, the external of the building had to be sheet-piled to permit excavation and removal of the bunker panels installed over 20 years ago. There were a couple of hitches in this process, for example pile driving 'impacted' on the PET camera, which was somewhat alarming to the patients.

A check of the camera performance criteria determined that it could safely withstand the vibrations being experienced. The existing bunker floor had extra concrete that was additional to that documented on the 'as constructed' drawings. It took some considerable effort to remove this latent condition.

The delivery of the cyclotron and hot cells was finally determined and the cyclotron delivered seven days ahead of the required insertion date – a commendable outcome considering all the variables. In fact, the cyclotron and hot cells arrived on the same ship.

The 26-tonne cyclotron was inserted on 11 April 2003. Qualified riggers and special equipment removalists managed this work. The first hot cell was inserted on the 2 April 2003. A week later, the Comecer team arrived from Italy to install and commission the remainder of the hot cell equipment. The goodwill by all parties during this period was commendable and demonstrated how comprehensive communication and co-ordination can achieve successful outcomes. This process did

incur some variations to the designed layout, but ultimately resulted in a good result for the facility. Although all tender drawings had been sent to the manufacturers, the team on the ground had other ideas. Much of this related to the fixed position for lead shielding for the incoming product lines. At 3.5 tonnes, these hot cells could not be moved at will. The hot cells were commissioned on 17 April 2003 and the Italian team left.

The next milestone was the arrival of the Belgium cyclotron commissioning team. This team was made up of various specialists, each required at a particular stage of the commissioning process. Therefore, it was extremely important to have a guaranteed date for them to proceed on the eight-week commissioning phase. After some intense work and several meetings, the Belgians were convinced that they could proceed. The team arrived on 9 June. The Australian agent also had obligations in having the radiation monitoring equipment operational by this date. These monitoring probes were placed in the bunker, laboratory and exhaust ducts. All outputs were connected to the PLC. The builder completed all works, mainly outside the bunker zone, and was awarded practical completion on 30 June 2003.

The IBA team commissioned the cyclotron on July 2003. A first batch of 'trial' FDG was manufactured on July 2003.

Operational Documentation

The Department of Medical Technology and Physics (MT&P) has been required to prepare comprehensive documentation for the maintenance and operation of this facility and has to satisfy the requirements of the WA Radiation Safety Council and the Therapeutic Goods Administration. A collaborative working group was also formed between the Engineering Department and MT&P to prepare controlled documentation for facilities management staff should there be any requirements to enter the area, for example fire or other engineering alarms. The area is under secure access control and there are times when no-one can enter the bunker due to radiation hazards, whilst the GMP laboratory requires full clean room clothing to be worn before entry is permitted.

The A\$8.885 million facility is now fully operational (the final cost of the works component was A\$1.8 million) – the result of a comprehensive collaborative team effort that has created one of the best cyclotron/GMP laboratory facilities anywhere.

The physicists are already planning the next step in the research field, and nuclear medicine physicians are planning their CT/PET system. Facilities management will undoubtedly be involved closely in the procurement of this enhanced modality. ■