SUBMISSION TO PARLIAMENTARY STANDING COMMITTEE ON PUBLIC WORKS

Proposed
Redevelopment of Radiopharmaceutical Production Building No 23
at Lucas Heights, Sydney

June 2003

Overview

1. As Australia's national nuclear research and development organisation, ANSTO's responsibilities include the operation of the HIFAR nuclear research reactor and the National Medical Cyclotron, to produce radioisotopes for use in medicine, industry and research. ANSTO estimates that, in 2001-02, some 475,000 Australians used its radioisotopes in the course of nuclear medicine procedures.

2. A replacement research reactor (RRR) is now being constructed, and is expected to be commissioned in 2005-06. One of the objectives of the RRR is to maintain and enhance health care benefits provided to the community through the provision of reactor-produced medical radiopharmaceuticals and to ensure security of supply over the next 40 to 50 years. To this end, it will have a much greater production capacity for radioisotopes.

3. The radiopharmaceuticals division of ANSTO is Australia's sole manufacturer of radioisotope products. ANSTO's annual turnover from radiopharmaceutical production grew at about nine per cent per annum from 1994-95 to 2001-02, when it amounted to about $20 million. ANSTO's radiopharmaceutical production activities are regulated by the Therapeutic Goods Administration of the Department of Health and Ageing and other regulatory bodies, and products must be produced under the Australian Code of Good Manufacturing Practice for Therapeutic Goods. Radiological safety is regulated by the Australian Radiation Protection and Nuclear Safety Agency.

4. The manufacture of radioisotope products is largely conducted in Building 23 at the Lucas Heights Science and Technology Centre. Building 23 was planned as a research facility but it has evolved into a full production facility. Building 23 and its current production facilities are not capable of meeting projected needs. There is a pressing need to streamline the production flow and materials handling, and to improve production capacity based on expected growth in demand. The present layout, facilities and services infrastructure reflect their incremental development. This has led to increasing OH&S issues, brought about by ageing infrastructure, inefficient production workflow, inability to significantly increase production, and inflexible, outmoded and inadequate materials handling solutions. Present work methods are manually based and labor intensive.

5. The preferred option is an extension to the North and East of the existing Building 23 on three levels. The complex will comprise modern quality controlled chemistry

laboratories, service and instrumentation rooms, production clean room facilities, packaging and dispatch facilities, stores and component wash bays. It will also include modifications to existing microbiological and clean rooms, intermediates solutions preparation cleanrooms and a sterilisation room. The project will also provide amenities and support facilities, as well as roadwork extensions, additional parking bays, landscaping, engineering and communication services.

6. The new development will satisfy all relevant Australian codes and standards, and will be built according to best practice principles in the pharmaceutical industry. It will provide for improved work methods and production efficiency through the introduction of appropriate materials handling devices, computerisation and automation.

7. The project is subject to the risk management processes of ANSTO. Risks for this project are being assessed for their potential impact on, for example, budget, schedule and performance.

8. The estimated cost for this proposal is $17.9 million (excl GST) +/-15% at March 2003 prices. It is planned that construction will take place over a period of approximately two years, commencing late in 2003 (timing is subject to receipt of the relevant approvals).

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IDENTIFICATION OF THE NEED

Background

9. As Australia's national nuclear research and development organisation, ANSTO is at the centre of Australia's nuclear expertise. It is a knowledge-based organisation that specialises in the delivery of specific scientific products and services to government, industry, academia and other research organisations.

10. ANSTO's responsibilities include the operation of Australia's national nuclear facilities. Two of these facilities, the HIFAR nuclear research reactor and the National Medical Cyclotron, produce radioisotopes for use in medicine, industry and research. HIFAR has been operating since 1958. The Government agreed to its replacement in 1997, and the replacement research reactor (RRR), which is now being constructed, is expected to be commissioned in 2005-06. It will have a much greater production capacity for radioisotopes.

Radioisotope Production

11. ANSTO's predecessor, the Australian Atomic Energy Commission, commenced production of radioisotopes for use in nuclear medicine in the 1960s. Since then, there has been a continuing growth in the use of nuclear medicine in Australia for diagnosis, therapy and palliation of pain. ANSTO is the main supplier of radioisotopes for use in nuclear medicine in Australia.

12. ANSTO estimates that, in 2001-02, some 475,000 Australians used its radioisotopes in the course of nuclear medicine procedures.

13. The radiopharmaceuticals division of ANSTO, trading as ANSTO Radiopharmaceuticals and Industrials (ARI), is Australia's sole manufacturer of radioisotope products. The radioactive products are supplied as radiopharmaceuticals[1], radiochemicals and sealed radiation sources for use in nuclear medicine as diagnostic and therapeutic aids, and for use in industry and research.

[1] A radiopharmaceutical is a biologically active chemical compound that incorporates a carefully selected radioisotope and is suitable for medical usage. Each radiopharmaceutical is designed to target a selected organ, such as heart, lungs, brain or bones. Radiopharmaceuticals can be ingested by inhalation, or as solids or liquids through the mouth, or by injection. The radiation then provides information to assist diagnosis, or has therapeutic or palliative impacts.

ANSTO's annual turnover from radiopharmaceutical production grew at about nine per cent per annum from 1994-95 to 2001-02, when it amounted to about $20 million. ANSTO's radiopharmaceutical production activities are regulated by the Therapeutic Goods Administration of the Department of Health and Ageing and other regulatory bodies, and must also meet the standards of bodies such as the US Federal Drug Administration. Products must be produced under the Australian Code of Good Manufacturing Practice for Therapeutic Goods.

14. Over the last few years the increase in demand for radiopharmaceutical products has resulted in the formalising and refining of production operations. These have been focused on the identification of short-term goals and improvements to satisfy immediate needs, within the context of existing occupational health and safety arrangements.

15. For the next five years, ANSTO's corporate projections are focused on the improvement of its position in both the Australian and international marketplaces. The five-year plan outlines strategies to prepare ANSTO for the opportunities provided by the RRR. One of the objectives of the RRR is to maintain and enhance health care benefits provided to the community through the provision of reactor-produced medical radiopharmaceuticals and to ensure security of supply over the next 40 to 50 years.

The Need for the Proposal

16. The manufacture of radioisotope products is largely conducted in Building 23 at the Lucas Heights Science and Technology Centre (LHSTC). Building 23 is located adjacent to the HIFAR reactor, within the highly protected area of the LHSTC, and close to the site of the RRR.

17. Construction of Building 23 began in 1959, and it has since been subject to an almost continuous process of modification and addition. This facility (and the process and equipment) was planned as a research facility but has evolved into a full production facility. Building 23 and its current production facilities are not capable of meeting projected needs. There is a pressing need to streamline the production flow and materials handling, and to improve production capacity based on expected growth in demand.

18. The present layout, facilities and services infrastructure reflect their incremental development. This has led to increasing OH&S issues, brought about by ageing infrastructure, inefficient production workflow, inability to significantly increase

production, and inflexible, outmoded and inadequate materials handling solutions (for example, unnecessary double handling of heavy lead shielded product containers, etc.).

19. Present work methods are manually based and labor intensive, but there is a clear intention within ANSTO to improve work methods and production efficiency through the introduction of appropriate materials handling devices, computerisation and automation.

Masterplan Objectives

20. A Strategic Masterplan study on Building 23 has been carried out to meet the following objectives and to provide viable options for the redevelopment of the facility, to:
    - Optimize the use of the existing production building;
    - Respond to a range of Occupational Health and Safety (OH&S) issues, including radiological issues, and ensure ongoing compliance with Comcare obligations;
    - Provide complete segregation of industrials isotopes and radiopharmaceuticals products;
    - Improve the current production operation and process, and to enhance the production output and efficiency of the facility to meet the projected demand for radiopharmaceuticals and radioisotopes for use in nuclear medicine and industry;
    - Provide radioisotope production capacity that will enable ANSTO to meet demand for many years to come;
    - Comply with the requirements of regulatory authorities such as the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), which has responsibilities in respect of radiological safety, the Therapeutic Goods Administration (TGA) of the Department of Health and Ageing and the US Federal Drugs Administration (both of these bodies have responsibilities in respect of the safety and proper manufacture of pharmaceutical products); and
    - Comply with security obligations for the effective control of radioactive materials.

Masterplan Study Outcomes

21. The outcomes of the Strategic Masterplan study are summarised as follows:
    - Several options have been examined for the future redevelopment of the ANSTO production Building 23, and all options can be accommodated without major disruption or downtime to the current manufacturing facilities.

- The existing personnel and materials flows were compared to the proposed future arrangements. The examination has demonstrated the improved logic behind the solutions adopted to achieve optimum OH & S as well as Good Manufacturing Practice to comply with current pharmaceutical production practice.
- The issues of maintenance and waste control have also been addressed in the proposals by focussing on the materials flow throughout the facility.
- Process engineering has been designed to accommodate improved technologies and automation.
- Linear process flows will prevent duplication in handling and cross contamination, and will result in optimal personnel and maintenance controls, and considerable improvements in efficiency.
- For the preferred option, a plan for the building extension and services upgrade and improvement, which allows for future extension, has been developed.

22. The proposal was challenged through a Value Management Study led by an independent group. The suitability and scope were confirmed.

Preferred Option

23. Several options have been examined, of which the proposed new extension and link to the existing Building 23, was the preferred option. The options were assessed in terms of:
    - Financial impact (value for money aspects)
    - A range of impacts based on achieving the outcomes of the Masterplan study.

24. The preferred option is described below (see next section). The success of this option requires some reconfiguration and refurbishment of the existing process building. The ANSTO internal Safety Approval Committee has reported on the concept phase, and its comments/recommendations have been taken into account as the proposal has developed.

25. The advantages and disadvantages of this option are summarised in broad terms below:

    Advantages
    - Minimal impact on current site operations;
    - Isolated construction zone for new buildings;
    - Simplified process flows (both materials and personnel);

- Best practice in pharmaceutical facility design;
- Capacity for expansion in all areas;
- Easily linked to existing facility; and
- Potential for flexible implementation.

Disadvantages

- Demolition and relocation of existing delay tanks for liquid radioactive effluent; and
- Minor reconfiguration of current production to maximise efficiencies.

26. Total project cost has been estimated at $17.9 million +/-15% (excluding GST). Funds for the project will be sourced from ANSTO's own resources – ie, no additional appropriation funding will be required.

27. The procurement process for the project is outlined in Appendix 1. It is planned that construction will take place over a period of approximately two years, commencing late in 2003 (timing is subject to receipt of the relevant approvals). Construction will have minimal impact on current site and/or radioisotope production operations.

28. It is planned that the project will be completed around the time the RRR is being commissioned. This will enable ANSTO to make full use of the RRR's capabilities, both by introducing a broader range of radioisotope products and services as quickly as possible and by satisfying steadily increasing demand for the existing range of products and services, while putting in place improved OH&S arrangements for the relevant staff.

Description of Preferred Option

29. The proposal comprises an extension to the North and East of the existing Building 23 on three levels.

30. The complex will comprise modern quality controlled chemistry laboratories, service and instrumentation rooms, production clean room facilities, packaging and dispatch facilities, stores and component wash bays. It will also include modifications to existing microbiological and clean rooms, intermediates solutions preparation cleanrooms, and a sterilisation room.

31. The complex will also provide amenities and support facilities. These facilities will include a new building entry including male and female locker rooms, bulk consumable and secure stores, maintenance areas, air locks and building services plant rooms.

32. In addition, associated roadwork extensions, additional parking bays, landscaping, engineering and communication services will be provided. Roadworks will be needed to serve the development and to ensure safe movement for vehicles and pedestrians using the precinct.

Other Options

33. Several options were considered, apart from the preferred option (see appendix 2). These were:
    (a) Expansion of existing Building 23 to the south
    (b) Expansion of existing Building 23 to the west;
    (c) Demolition of existing structure and building of new facilities;
    (d) Combination of demolition/refurbishment and new building;
    (e) Construction of new production facility off site;
    (e) Relocation to alternative facility; and
    (f) "Do Nothing" and maintain current production and materials flow.

Project Support

34. Within ANSTO, the proposal has been developed with extensive consultation and is supported by the following:
    - Radiopharmaceuticals
    - Safety and Radiation Sciences
    - Engineering Services
    - Nuclear Technology, for interaction with the RRR
    - Government and Public Affairs
    - CEO
    - ANSTO Board

35. ARPANSA has indicated that they fully support the concept of redeveloping and upgrading the ANSTO production facility. Activities associated with the design, construction, commissioning and operation of the redeveloped Building 23 will be regulated under the *ARPANS Act 1998* and the *Therapeutic Goods Act 1989*. Other stakeholders will be consulted.

Best Practice in Pharmaceutical Manufacturing

36. The new development will be built according to best practice principles in the pharmaceutical industry. This will cover processes, techniques, and innovative use of technology, equipment and other resources.

37. Recent developments in processing methods and equipment in the pharmaceutical and radiopharmaceutical industries have been investigated in the context of the project. Developments in the manufacture of hazardous and sterile substances are focussed on
    - contained or isolated processes that utilise primary containment barriers, and
    - isolator technology to minimise both operator exposure and physical size of the cleanroom environment.

38. The upgraded facility will incorporate the relevant technologies as part of ensuring that ANSTO utilises best practice in terms of code compliance and maintenance of production.

Staffing of Facility

39. The proposal requires no additional staff over current levels. It is anticipated that staff numbers may increase by five percent over the next 5 years. The introduction of automated productions lines is expected to maintain staffing at current levels.

40. The consolidation of activities within the proposed new facility will maximise the flexibility of the accommodation and enhance the opportunities for future changes within and between production groups and programs.

Environment and Heritage Issues

41. ANSTO has referred the proposal to the Department of the Environment and Heritage for consideration of whether the proposal is likely to result in a significant environmental impact in terms of the *Environment Protection and Biodiversity Conservation Act 1999*.

42. In the particular case of airborne radioactive emissions, in the context of the environmental assessment of the RRR project in 1999, ANSTO gave a commitment that radioactive gaseous emissions discharged via stacks from buildings associated with radiopharmaceutical production would not increase above the levels that then existed, regardless of any future production increases. ANSTO has achieved a

significant reduction in airborne emissions since it entered into that commitment. Operations within the proposed facility will be covered by this commitment.

43. In general, construction of the new extension will result in direct, short term, localised and small-scale impact to soils, air quality, flora and fauna, traffic and transport infrastructure and services, noise and visual and landscape. Management initiatives will restrict any impact on surface and groundwater quality and on general waste management.

44. Pursuant to Section 7A of the Australian Nuclear Science and Technology Organisation Act 1987, ANSTO is exempt from the application of State or Territory laws where those laws relate, among other things, to the environmental consequences of the activities of ANSTO.

45. The proposed building site covers an area of approximately 1700 square metres which, at present, includes concrete and asphalt hardstand and lawn. There are no national or aboriginal heritage issues relating to it.

Zoning and Approvals

46. Pursuant to Section 7A of the Australian Nuclear Science and Technology Organisation Act 1987, ANSTO is exempt from the application of State or Territory laws where those laws relate, among other things, to the use of land.

Provision for Disabled People

47. Safety, security, operational and regulatory requirements limit the extent to which disabled access can be fully implemented in the controlled operational areas of the development. Nevertheless, the needs of disabled persons will be taken into account to the extent practicable in the design of these areas. Ramps will be provided to the new entry of the new production Building 23. Appropriate toilets will be provided in the administration area of Building 23 after completion of production expansion development.

Risk Management

48. The project is subject to the risk management processes of ANSTO. ANSTO has a risk management policy and framework consistent with the Australian Standard 4360:1999. This framework has been benchmarked favourably against Comcover

better practice principles. It is ANSTO policy that all major projects assess risks, identify risk owners and develop action plans to mitigate identified risks. Risks for this project are being assessed for their potential impact on, for example, budget, schedule and performance. Risks are discussed on a regular basis at relevant ANSTO management meetings, including the Building 23 Project Monitoring Group. The ANSTO Board Audit Committee has an oversight role on ANSTO risk management.

TECHNICAL INFORMATION

Site Location

49. The site for the proposed redevelopment of Building 23 will be located within the 70 hectare LHSTC, on a site adjacent to the existing HIFAR reactor. The LHSTC is situated in the local government area of Sutherland Shire, approximately 30 km south-west of Sydney's central business district.

Design Objectives

50. The design aims to provide the facilities required to undertake leading edge radiopharmaceutical production activities within a comfortable and safe working environment. A second and important aim is the provision of an environment to continue to meet the regulatory requirements of the TGA and ARPANSA.

General Design Principles

51. The new building, services and external infrastructure will be designed and built to meet all relevant Australian Standards, the Building Code of Australia and health and safety regulations. It will also comply with appropriate international standards and requirements.

52. Design principles are:
    - Prevention or exclusion of any sort of impurities in sterile manufacturing areas;
    - Logical product, personal and materials flow;
    - Minimising materials handlings steps and paths;
    - Provision of adequate protection against contamination;
    - Long term flexibility – multiple use of production areas;
    - Adaptability – easy conversion;
    - Simplicity of maintenance – with easily accessible services;
    - Simplicity of Cleanliness – with ease to decontaminate; and
    - Durability of materials – withstanding heavy loads from transport devices, etc.

53. The new generic production area layout, personnel and materials flow has been developed through consultation with user representatives and staff. All relevant staff have been fully involved in the planning of the new development.

Scope of Works

54. The works encompass the construction of a three-storey production extension to the North and to the East of the existing Building 23, including plant rooms and controls rooms.

55. Base Building will include:
    - Integration of services into the base building works, including electrical, mechanical, communication, security, fire and hydraulic services;
    - A building management system, and building environmental and radiation monitoring systems;
    - Data installation that is compatible with site information technology requirements and to specified manufacturing requirements; and
    - Air conditioning zoning to clean room environment to enable ease of change with spare capacity for additional package units for shelled production areas; and spare electrical capacity within the floor distribution boards to allow for the fitout without having to add floor distribution boards.

Allocation of floors

56. Facilities on the **lower ground level** of the new and extended complex will include:
    - Product lead container and components washing;
    - Materials receiving staging area;
    - Active waste store;
    - Change and amenities rooms;
    - Waste bin store;
    - Non active waste store;
    - Electrical switch room;
    - Building management control room;
    - Landscaped courtyard;
    - Secondary packaging;
    - Product Dispensing room;
    - Recall, rejects, returned store;
    - Secure store;
    - Consumable store;
    - Air locks;
    - Goods and personnel lifts; and
    - Office areas.

57. Facilities on the **ground level** will include:
    - Main entry to clean production rooms;
    - Male and female locker and change rooms;
    - Maintenance workshop;
    - Multipurpose production clean room;
    - Intermediate preparation clean rooms;
    - Quality control laboratory;
    - Quality instrumentation room;
    - Thallium/Gallium production clean room;
    - Gentech^{R} Assembly and Sanitation room;
    - Sterility testing clean room;
    - Autoclave room;
    - Female and male gowning area;
    - Additional production areas;
    - Corridors and other service areas;
    - Air locks, and goods and personnel lifts; and
    - Office areas.

58. The **mezzanine** and **first level** are dedicated to maintenance and plant rooms for all building services and support services.

Floor Area

59. The proposed development will comprise 3636 square metres of useable floor area, including corridors and building structure. Including the plantroom areas, there will be approximately 4220 square metres of floor area.

Car Parking

60. The new complex will be provided with 6 car parking spaces, mainly for maintenance or delivery personnel.

Structure

61. The building foundations are designed for safe operation under seismic, dead, live, vibration, settlement and equipment loads over the life of the facility and are expected

to be concrete column pads socketed into sandstone rock. It is anticipated that piling for foundations will not be required.

62. The building will be reinforced concrete column and slab construction to tolerate 5000 kg/m^2 for new production cells. In general, floors will be monolithic concrete finish, with epoxy or vinyl floor finishes

Services and Ceiling Height

63. Co-ordination of services with structural columns and floor slab/beam profiles will be achieved through utilisation of ceiling space above production areas with corridors for major duct runs. The floor to floor clearance planned for the project is approximately four metres.

Materials and Finishes

64. The facade of the production building will utilise a range of different building materials, namely colorbond^R on ground level and concrete and blockwork on the lower ground level, lightweight metal wall panels and glazing.

65. The appropriate selection of materials and finishes will meet the expected performance criteria, proper finish and cost requirements. The need to provide for contamination concerns from both other products (cross contamination) and from foreign matter as a result of materials finish wear or degradation will be addressed.

Floors

66. A seamless floor finish would be best suitable for cGMP and general cleaning capability. Essentially, there are two options in common use - sheet vinyl and self-levelling epoxy. Both finishes enable a continuous and virtually seamless integrated covering to the floor/wall junction.

Walls

67. The selection of wall finishes is dependent on the base wall finish, i.e. masonry, metal stud and lining or even sandwich panel, or any other proprietary system deemed suitable.

68. **Masonry**: concrete block or even solid poured concrete walls may be preferred. The ultimate finish should be smooth and easily cleaned regardless of the sub-base.

Smooth finishes can be achieved with hard plaster or sheet materials over the masonry finish. Concrete can be installed with a smooth finish suitable for a finishing coat of plaster or paint.

69. **Stud and wall lining**: timber or metal studs can be used to provide a lightweight system that is flexible, making it easy to reticulate services within a later enclosed wall system. This approach is readily demountable and enables easy refurbishment and alteration. It also allows for localised radiation shielding prior to final sealing of the wall cavity, subject to the extent and scope of the heavy lead shielding. The wall lining system can be either one or two layers of plasterboard, one layer plasterboard over (or under) fibre cement sheet subject to the requirements for impact protection, or a fibre cement wall lining system. A range of paint finishes may be used over the sheet material, with epoxy paint being the strongest and most hard wearing.

70. **Wall protection**: a range of options for wall protection exist. The option chosen would need to be compatible with the wall sheeting material and/or finish selected. The wall protection would be designed in conjunction with other floor or wall mounted fittings, such as stainless steel bollards, guardrails and wall railings. In addition, the application of wall vinyl over sheet material tends to protect the finished surface from scratching and abrasions from regular use and wear and tear.

Ceilings

71. Unless a concrete slab overhead is used as the base ceiling material, it is most likely that a suspended system of some description would be required. Typically sheet plasterboard or fibre cement fixed to a lightweight suspension system would be used. Alternatively, a ceiling tile system on a suspension system (either exposed or concealed), or a proprietary sandwich panel system that requires no finishing coatings or materials, could be utilised.

Roadworks

72. Proposed roadworks improvements include:
    - car park, bays; access road to Fermi Street;
    - manoeuvring areas and new loading areas; and
    - footpaths.

Mechanical Services and Systems

General

73. The control of the air quality and air conditioning is critical to the health and safety of the occupants of both the facility and the surrounding areas. The nature of the radioactive materials handled within the facility, together with the stringent guidelines that have to be complied with when manufacturing therapeutic goods, necessitate the use of specialised mechanical equipment and control systems. The entire building will be designed around the mechanical systems and production process, to ensure that the required internal design conditions can be achieved.

74. Primary confinement areas will be kept at a negative pressure in order to provide radioactive containment.

75. In order to comply with cGMP codes, the entire manufacturing process has to be carried out within a clean environment. This is achieved by a building and mechanical services design that incorporates specialised pressure regimes between the different areas.

Air conditioning, ventilation and exhaust systems

76. The air conditioning to the various areas of the building will be provided by a separate mechanical plant, in order to ensure that no cross-contamination between different products and areas can occur.

77. Chilled water air handling units will be used for the cooling requirements of the air conditioning system while the heating function will be met by using electrical heating systems. The air conditioning systems, together with the necessary exhaust systems, provide the required building pressurisation regimes.

Central chilled water system

78. This system operates on the principle of pumping cold water from the centrally located chilled water generator to an air cooling coil in the air handling unit serving each area. Conditioned air is then supplied to the internal space in order to maintain the required internal conditions. The return air from the space is then either re-cooled and supplied back to the space or exhausted to atmosphere, depending on the requirements of the individual areas. In order to reduce running costs, it is desirable to re-circulate as much of the conditioned air as possible.

Water-cooled package units

79. Individual air conditioning units will serve each area. The units vary in size to suit the area and will be mounted within an internal plant room. The heat removed from the space is dissipated to the environment by air cooled condensers mounted external to the building.

Electrical heating

80. The existing facility is served by electrical heating systems, and the continued use of this type of system would be the lowest cost option. This type of system is simple to install and operate.

General Mechanical Plant Room

81. A main plant room located on Level 1 provides a large area for the extensive plant requirements. It allows for easy access and ensures that the 'dirty' plant areas are segregated from the 'clean' production areas. There is also an allowance for some mechanical plant to be located in the lower level.

General Exhaust systems

82. All air that is removed from within the production facility shell and discharged to the environment will be appropriately filtered and treated to ensure that radioactive contamination that escapes from the facility is as low as reasonably achievable (see also para 37).

Gas and compressed air service

83. The existing liquid nitrogen source, and reticulation for nitrogen gas, vacuum and compressed air will be extended to the new areas and modified in locations where required throughout the existing facility.

Roof and Exhaust Stack

84. The architects intend to create a simple curved metal roof for the new expansion of Building 23.

85. The new expansion ventilation system will discharge to atmosphere via a stack expected to be approximately 12 metres higher than the building. Discharges through the stack will be treated to remove materials and will be continuously monitored in accordance with regulatory requirements (see also para 37).

Electrical Services

Power Supply - Existing Building

86. The current services indicate that no spare capacity is available in the existing low voltage (415/240 volt) system to cater for the new extension. The changes to the services required to the existing building as proposed will be accommodated by the existing power supply as some of the existing mechanical load will be transferred to the new building.

Power Supply - New Building

87. The available information on the existing power supply indicates that there is minimal spare capacity to cater for new plant. Therefore the new building will require a separate power supply to be provided from a local sub-station. Provision has been made for a local substation, to cater for the new extension as well as any future expansion.

88. A main switchboard will be installed in a new main switch room located on the lower level of the new building. A number of distribution boards will be located throughout the building to provide power to the various items of plant, process equipment and general power requirements. The power for the mechanical plant will be supplied from local switchboards located in the mechanical plant areas.

Voice and Data systems

89. The existing telephone and public address systems will be extended to cover the new areas as required. The site telephony system has been recently upgraded.

90. An integrated voice/data cabling system will be provided to link each voice and data outlet in each building back to the communications closet in the building.

Building Management System

91. A proprietary Building Management System will monitor and/or control all building engineering services. The system will cover HVAC plant and equipment, airflows, filter performance, fume and other exhaust systems, heating and chilled water reticulation, Constant Temperature Rooms and artificial lighting. The system will be programmable with graphics interfaces for full zone control and will incorporate facilities for external monitoring and energy conservation. It will be capable of expansion.

Fire detection, fire alarm and security systems

92. A new fire detection and fire alarm system will be installed and interconnected with the existing system to ensure that the entire facility operates as a single unit.

93. There will be a building security system installed with secure card access to control and monitor access to certain production areas. Continual monitoring of personnel time and location within the facility can also be performed. The centralised receiving and dispatch and the single entry into the facility allows for easy implementation of a security system.

Hydraulic Services

Hot and cold water systems

94. The main supply of cold water for the new extension will be derived from the existing building. Hot water will be generated locally within the new areas to cater for change rooms, showers and sinks. Provision for a number of safety showers has been made throughout the new facility.

95. Due to the nature of the production being undertaken, only limited provision for hot and cold water within the area has been allowed for at this stage.

Stormwater

96. The new extension of building 23 will necessitate additional stormwater control systems for existing drainage catchments, with implementation of contouring, bunds, retention ponds and stormwater litter collection. The system will be integrated into the existing ANSTO stormwater system.

Fire Services

97. The new building will be provided with fire sprinkler protection. A new hydrant and hose-reel system will be installed throughout the new building and the existing system will be upgraded. It will fully comply with all relevant codes.

Fire water Retention

98. Fire water retention around the building will be achieved using hard stand bunding and profiled to provide a catchment for the water. External storm water drains will be fitted with automatic isolation valves to isolate the drains in the event of a sprinkler or hydrant alarm.

99. Storm water retained in this way will be subsequently released at a controlled rate into the site liquid waste treatment system, once testing has established the presence or absence of contamination.

Liquid and Solid Wastes

Liquid Wastes

100. Liquid waste water from the production extension of Building 23 will be collected and managed in accordance with standard arrangements for the LHSTC site. The effluent will be segregated into three categories:
    - Non-radioactive sewage;
    - "B" line low level waste water, arising from "active" drains in the quality control laboratories, Gentech washing areas and other areas where radioactive materials are routinely handled. This waste contains low levels of beta and gamma emitting radionuclides;
    - "C" line trade waste effluent, arising from areas in which radioactive materials are not normally handled.

101. The LHSTC site infrastructure includes delay tanks for collection from buildings, with pipework to the site treatment facilities which are connected to the Sydney Water Corporation's sewer tunnel system. Before release to the sewer system, the wastewater quality must satisfy requirements set out in ANSTO's Trade Waste Agreement with Sydney Water Corporation.

Intermediate level solid waste

102. Short-lived intermediate level solid waste is produced during the normal radiopharmaceuticals manufacturing process. Initially, the waste is stored, with appropriate shielding, in 2 litre cans in the Hotcell area of Building 23. The waste is then transferred to Building 27 for longer-term storage. These arrangements will continue in force after the extended Building 23 is operational.

Low level solid waste

103. This waste is produced from a range of activities in the radiopharmaceuticals manufacturing process. It is collected, processed and stored in Building 59. Again, these arrangements will continue in force after the extended Building 23 is operational.

Materials Handling Equipment

104. An automated motorised transport system will be provided. This system will distribute product lead pots automatically within the larger facility from production rooms on the ground level to packaging/dispatch rooms on the lower ground level.

105. The facility layout will have the capability for future development of the materials handling systems equipment.

106. In addition, a robotic packaging cell including conveyors will be provided in the packaging area. Operators will then no longer be exposed to radiation while packaging radiopharmaceutical products.

Energy Conservation Measures

107. Consideration will be given to the incorporation of passive energy conservation measures into the building and landscape design, and active measures into the design of the mechanical, electrical and hydraulic services to reduce the usage of conventional fossil fuel energy. Measures to be considered will include:
    - North facing windows, screened to provide control;
    - Recovering energy from building exhaust system and using it for the precondition of the building fresh air system;
    - Shading to the east and west windows, to control solar heat gains;
    - Thermal insulation, to reduce heating and cooling loads;
    - Significant daylight incorporated into the design, to minimise the use of artificial lighting;
    - Building management system, to operate, control and monitor engineering services;
    - Variable speed drives for all variable air volume handling plant and secondary chiller water and heating water pumps;
    - Use of long life low energy light fittings; and
    - Measures to reduce water consumption - water flow control tapware, dual flush WC pan cisterns, programmable boiling water units, etc.

Technical References

108. Relevant technical references are listed at Appendix 3.

Appendices

APPENDIX 1

Building 23 Upgrade Procurement Process

On the 13th of March 2002 a contract was signed with S2F Pty Ltd (ABN 68685 634 27) to develop the design engineering plan for the upgrade of Building 23 at ANSTO Lucas Heights.

This followed an earlier tender process and evaluation for the development of the project master plan. This process included responses from Pharma Direction, Moore and Cashell Australia, Connell Wagner, Sinclair Knight Merz and AHW.

S2F Pty Ltd was selected on the basis of the best value for money, considering their proven track record in design and construction of pharmaceutical facilities as reflected in the quality of the developed project master plan.

To assist in developing the detail design and as a forerunner to the construction phase, ANSTO researched the market for a suitably qualified construction manager with pharmaceutical experience. Proposals were invited from Austin Australia Pty Ltd and Hooker Cockram Projects Ltd and on the 17th of March 2003 a contract was signed with Hooker Cockram Projects Ltd (ABN 99004799508) to provide these consultancy services.

Subject to satisfactory performance during the detail design phase, it is proposed that Hooker Cockram act as Construction Manager for the construction phases of the project on the basis of developing a guaranteed maximum price. This price would be developed following a selective tendering process for each work package.

Following an independent quantity survey of the developed guaranteed maximum price, and acceptance by ANSTO, the construction phase would be let to Hooker Cockram on the basis of taking all risk on project overrun. Any savings would be split evenly between ANSTO and Hooker Cockram.

ANSTO has favoured this approach due to the specialised requirements of the project and the need to meet high industry standards.

APPENDIX 2

OPTIONS NOT PREFERRED

(1) Expand existing Building 23 to the south

The area to the south of the existing building, currently utilised as open space, has been identified as a viable option for future expansion. As the existing administration building separates this area from the main production complex it would be isolated from the existing manufacturing functions and amenities. A new link to the western end of the building may be established to integrate the production facilities.

Due to the degree of isolation, this extension would best suit administration functions and, if used as such, the existing office space would be converted into production area. Preliminary structural and services investigations indicate that the viability of this option is limited. Moreover, there would be only limited capacity for further expansion.

(2) Expand existing Building 23 to the west

Located adjacent to the west of the existing building is a landscaped area identified as a possible option for future expansion. An extension into this area would result in a circuitous traffic route from delivery to dispatch. This would not alleviate current congestion of materials, personnel and equipment flows.

In addition, the proximity of surrounding buildings restricts the size of the available area. These factors have led us to conclude that this option is not viable.

(3) Demolish existing and build new facilities

Due to the nature of radiopharmaceutical production and the difficulties arising from any interruption to production, this option is not considered viable. Furthermore, the cost would be substantially greater than the cost of the preferred option.

(4) Combination of demolition/refurbishment and new building

Similarly to option (3) above, the nature of radiopharmaceutical production and the difficulties arising from any interruption to production, and the likely cost mean that this option is not considered viable.

(5) Construction of new production facility off-site

Due to the radiopharmaceutical production, logistical (near the RRR), social, political and economic issues associated with such a relocation, this option is not considered viable.

(6) Relocate to alternative facility

Currently within Australia there is no such alternative facility.

(7) "Do Nothing" and maintain current production and material flow

The "Do Nothing" option is not considered viable, as ANSTO would be unable to meet increasing national demand for its radiopharmaceuticals or utilise the RRR's full capabilities. Nor would ANSTO be able to introduce significant production efficiencies or improvements to occupational health and safety arrangements.

APPENDIX 3

Technical References

ANSTO is committed to maintaining standards of radiation safety recommended by the International Atomic Energy Agency, the Australian National Health and Medical Research Council and the National Occupational Health and Safety Commission. ANSTO is also required to operate in accordance with the *ARPANSA Act* and *Regulations* as well as the *Occupational Health and Safety Act* and *Regulations*. In producing radiopharmaceuticals, ANSTO is also required to conform to the requirements of the Code of Good Manufacturing Practice produced by the Therapeutic Goods Administration and to the relevant standards of the FDA. The following codes and standards will be used as necessary and relevant in the design, construction and operation of the redevelopment of building 23.

Details	No.	Date	Publisher
Building Code of Australia with Amendments to No 10	BCA96	1996	Australian Building Codes Board
NSW Occupational Health and Safety Act and Regulations		1983	AGPS
Construction Safety Act and Regulations		1912	AGPS
NSW Workcover Administration Act and Regulations		1989	AGPS
ComCare Regulations			AGPS
Code of Practice - Ventilation of Radioactive Areas	AECP 1054	March 1993	AEA Technology
Technical Report Series	292	1988	IAEA
Technical Report Series	325	1991	IAEA
Pharmaceutical Inspection Convention (PIC/S) guide to GMP for Medicinal Products Annex 1 – Manufacture of Sterile Medicinal Products Annex 3 – Manufacture of Radiopharmaceuticals	PH 1/97 (Rev. 2)	10 August 2001	PIC/S Secretariat
Safety in Laboratories – Parts 1 to 7	AS/NZS2243	1990 to 1998	Australian Standards Association
Laboratory Construction Code	AS2982	199?	Australian Standards Association
Clean rooms and clean workstations Part 1; Principles of clean space control	AS1386.1	1989	Australian Standards Association
Clean rooms and clean workstations Part 2; Laminar flow cleanrooms	AS1386.2	1989	Australian Standards Association
Clean rooms and clean workstations Part 3; Non-laminar flow cleanrooms – Class 350 and cleaner	AS1386.3	1989	Australian Standards Association
Clean rooms and clean workstations Part 4; Non-laminar flow cleanrooms – Class 3500	AS1386.4	1989	Australian Standards Association
Clean rooms and clean workstations Part 6; Operation and inspection of cleanrooms	AS1386.6	1989	Australian Standards Association

Details	No.	Date	Publisher
Laminar Flow Cytotoxic Drug Safety Cabinets	AS2567	1994	Australian Standards Association
Laminar Flow Cytotoxic Drug Safety Cabinets – Installation and Use	AS2639	1994	Australian Standards Association
The use of Mechanical Ventilation and Air Conditioning in Buildings Part 1 – Fire and Smoke Control	AS1668.1	1998	Australian Standards Association
The use of Mechanical Ventilation and Air Conditioning Part 2 – Mechanical Ventilation for Acceptable Indoor – Air Quality	AS1668.2	1991	Australian Standards Association
Wiring Rules	AS3000	Current Ed.	Australian Standards Association
Acoustics – Application to Specific Situation	AS1055	1997	Australian Standards Association
Air Filters for Use in Air Conditioning and General Ventilation	AS1324	1996	Australian Standards Association
Classification of Hazardous Areas	AS2430	Current Ed.	Australian Standards Association
Ductwork For Air Handling Systems in Buildings	AS4254	1995	Australian Standards Association
High efficiency particulate air (HEPA) filters – Classification, construction and performance	AS 4260	1997	Australian Standards Association
Thermal Insulation of Pipework, Ductwork and Equipment – Selection, Installation and Finish	AS4426	1997	Australian Standards Association
Minimum Design Loads on Structures	AS1170	1993	Australian Standards Association
Supplementary Report to Senior Management Committee regarding request for specific additional information. Strategic Master plan Study		24 October 2001	S2F Pty Ltd