Modifications to

MACQUARIE UNIVERSITY PRIVATE HOSPITAL

Project Application MP 06-0172

SECTION 75W APPLICATION

Submitted to
NSW Department of Planning
On behalf of Macquarie University Private Hospital

Prepared by
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Nuclear Medicine

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1.0 Table of Contents

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2.0 Introduction

This report accompanies an application to the Minister of Planning under Section 75W of the Environmental Planning and Assessment Act 1979 (EP&A Act) to modify the Project Approval (MP 06-0172) granted by the Minister of Planning on 13 May 2007 and the subsequent modification of that approval granted by the Minister of Planning on 23 January 2008.

The Project Approval relates to the construction of a new private hospital, in two stages, on a site (referred to as Site 2) in Macquarie University Research Park, North Ryde.

The modification to the Project Approval relates to the PET Radiopharmaceutical Laboratory on level B2.

The proposed changes to the PET Radiopharmaceutical Laboratory are

- Increase in floor space from 420m^2 to 470m^2
- The addition of an unmanned goods hoist between levels B2 and B1
- Internal layout of area

The purpose of this report is to:

- Describe the proposed modifications
- Discuss/assess the potential environmental effects of the said modifications

This environmental assessment has been prepared by Cyclopet Pty Ltd on behalf of Macquarie University Private Hospital, a joint venture between Dalcross Hospital and Macquarie University, the proponent of this project.

3.0 Proposed Modifications to Project Approval

3.1 Existing Consent

On 23 January 2008, the Minister of Planning approved the modification to the Project Application (MP 06-0172) for the development on the subject site:

- Demolition of all buildings, structures and landscaping at No. 3 Technology Place;
- Staged construction of an 19,491.9sq.m, 208-bed, 6 storey private hospital at No. 3 Technology Place including basement car parking for 228 vehicles, associated site landscaping and infrastructure works and a 2 level pedestrian bridge across Technology Place (connecting to No. 2 Technology Place);
- Amendments to the basement, internal layout and facade of the building approved on No. 2 Technology Place; and
- Use of the proposed building at No.2 Technology Place as specialist consulting rooms and the like in conjunction with the private hospital at No. 3 Technology Place.

Condition A2 states that the development must be undertaken in accordance with the following plans and documentation:

Drawing No.	Revision	Name of Plan	Date
SITE 1			
MQA-A-P-B1	2	BASEMENT 1 PLAN	3 October 2006
MQA-A-P-G	1	GROUND FLOOR	3 October 2006
MQA-A-P-3	6	LEVEL 3	3 October 2006
MQA-A-P-E1	4	ELEVATIONS	3 October 2006
SITE 2 STAGE 1			
MACQ-A-PL-LOC	3	LOCATION PLAN	4 September 2006
MACQ-A-SITE	4	SITE PLAN	7 September 2006
MQB1-A-COL-P-B1	9	BASEMENT 1	14 September 2007
MQB1-A-COL-P-B2	8	BASEMENT 2	14 September 2007
MQB1-A-COL-P-G	8	GROUND	14 September 2007
MQB1-A-COL-P-1	8	LEVEL 1	14 September 2007
MQB1-A-COL-P-2	7	LEVEL 2	14 September 2007
MQB1-A-COL-P-3	7	LEVEL 3	14 September 2007
MQB1-A-COL-P-4	5	LEVEL 4	14 September 2007
MQB1-A-COL-P-5	7	LEVEL 5	3 October 2006

MQB1-A-COL-P-6	1	LEVEL 6	3 October 2006
MQB1-A-COL-P-R	1	ROOF	3 October 2006
MQB1-A-COL-E1	10	ELEVATIONS	14 September 2007
MQB1-A-COL-E2	9	ELEVATIONS	14 September 2007
MQB1-A-COL-S1	8	SECTIONS	14 September 2007
MQB1-A-COL-S2	7	SECTIONS	14 September 2007
MQB1-A-SDG	1	SHADOW DIAGRAM	26 September 2006
SITE 2 STAGE 2			
MQB2-A-COL-P-G	3	GROUND	14 September 2007
MQB2-A-COL-P-1	2	LEVEL 1	14 September 2007
MQB2-A-COL-P-2	2	LEVEL 2	14 September 2007
MQB2-A-COL-P-5	1	LEVEL 5	3 October 2006
MQB2-A-COL-P-6	1	LEVEL 6	3 October 2006
MQB2-A-COL-P-R	1	ROOF	3 October 2006
MQB2-A-COL-P-E1	3	ELEVATIONS	14 September 2007
MQB2-A-COL-P-E2	3	ELEVATIONS	14 September 2007
MQB2-A-COL-P-S1	3	SECTIONS	14 September 2007
MQB2-A-COL-P-S2	2	SECTIONS	14 September 2007
MQB2-A-SDG	1	SHADOW DIAGRAM	26 September 2006
LA 01	A	LANDSCAPE PLAN	6 June 2006
LA 02	A	LEVEL 4 ROOF GARDEN	6 June 2006

3.2 Proposed Amendments

The following modifications are changes proposed, which are illustrated on the attached drawings (Refer to Appendix 1).

1. Increase in the PET Radiopharmaceutical Laboratory on Basement 2

The proponents wish to increase the area of the Radiopharmaceutical Laboratory from the approved 420m^2 to 470m^2. This increase is to accommodate a gas cylinder store which is essential to the operation of the Radiopharmaceutical Laboratory. The gas cylinder store was originally proposed to be on level B1, but it was agreed that it would be better sited on level B2 next to the Radiopharmaceutical Laboratory. A detailed brief on this facility and its operation is contained in Appendix 2.

As the proposed extension to the Radiopharmaceutical Laboratory is located underground it will have no impact on the exterior of the building (ie in terms

of the modifications to the façade or expansion of the building footprint) but will increase the floor area.

2. Install an unmanned hoist between levels B1 and B2

The proponents wish to install a goods hoist between levels B1 and B2 for the transport of the gas bottles. The goods hoist is essential to having the gas bottle store on level B2. Without this hoist the gas bottles could not be moved to and from the gas bottle store on level B2.

This hoist is within the Radiopharmacy and rises to the car park on level B1. The hoist will require a room on level B1 to enclose the upper level of the hoist to satisfy fire regulations. This room will occupy 1 car parking space and thus will decrease the car parking spaces available on site by 1 space.

As the proposed hoist is below ground and within the existing footprint it will have no impact on the exterior of the building.

3. Internal layout of rooms within the Radiopharmacy

The proponents wish to fit out the Radiopharmacy shell with a number of rooms to enable the production and handling of radiopharmaceuticals. The operation of the Radiopharmacy requires 3 clean room laboratories, a quality control laboratory, a packaging room, an office and amenities.

The requirements of this area have been allowed for in the original building design.

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4.0 Assessment of Modifications

4.1 Section 75W Modification of Ministers Approval

Under Section 75W of the *Environmental Planning and Assessment Act 1979 (EP&A Act)* a proponent may request the Minister to modify the Project Approval.
Modification of an approval means changing the terms of the Ministers approval, including:

a) revoking or varying a condition of the approval or imposing an additional condition of the approval, and
b) changing the terms of any determination made by the Minster under

4.2 Environmental Effects

This increase in floor space and hoist will not have any environmental effects other than those already mentioned in the approved modification to the Project Approval of 23 January 2008.

Visual Impact
As the increase in floor area is underground there will not be any visual impact.

Traffic and Car Parking
The increase in floor space will not result in an increase in people required to operate the Radiopharmaceutical Laboratory or visitors. Thus no extra car parking or traffic movements occur from this extra floor space.

Waste minimisation and waste management
There is no change to the waste management or generation due to the increase in floor space

BCA Compliance
The proposed modifications have been checked against BCA and are capable of compliance. The development will be privately certified for BCA compliance. The package of documentation forming the Construction Certificate (CC) will demonstrate full BCA compliance.

Impact on the environment
The Cyclotron and Radiopharmaceutical Laboratory will comply with relevant State legislation, regulations and statutory requirements. Plans and specifications of the facility will be assessed for radiation protection by a certified physicist and licensed by the EPA.

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5.0 Conclusion

The proposal to modify the Project Approval for Macquarie University Private Hospital has been assessed in accordance with relevant requirements of Section 75W of the EP&A Act.

The assessment of the proposal has demonstrated that the proposed modifications have no impact on the previous Project Approval conditions other than a minute increase in floor space underground and the reduction of available car parking by 1 space.

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6.0 Appendix 1 – Design Drawings

Drawing No.	Revision	Name of Plan	Date
DA01	01	SITE PLAN	23 January 2009
DA02	01	BASEMENT B2 FLOOR PLAN	23 January 2009
DA03	01	HOIST LOBBY PLAN BASEMENT B1	23 January 2009
DA04	01	TENANCY FLOOR PLAN BASEMENT B2	23 January 2009

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7.0 Appendix 2 – PET Radiopharmacy Brief

Macquarie University Private Hospital PET Radiopharmacy

Introduction

The aim is to locate the facility (including the Cyclotron) within the confines of Macquarie University Private Hospital so that the researchers, specialists in various medical fields and nuclear medicine practitioners can maximize the benefits associated a cyclotron located next to an imaging centre, particularly as it allows researchers and physicians alike to capitalize on a cyclotron's ability to produce short-lived imaging radioisotopes such as Carbon 11, Oxygen 15 and Nitrogen 13 in addition to the primary agent FDG. Additional benefits will be gained from accessing the pool of intellectual excellence located at the new Macquarie University Private Hospital in terms of ongoing research, as well as the provision of cutting edge medicine.

Carbon 11 is the PET (positron emission tomography) radioisotope of choice to evaluate targeting molecular entities. It is a radioisotope that is chemically identical to components of biologically active molecules under evaluation as targeting agents. Its production and incorporation into PET molecules will provide the basis for future products. It is currently used for labelling molecules to evaluate their biodistributions by research scientists and clinicians.

The facilities and scientific capabilities will be available to researchers, collaborate in the investigational studies to evaluate new moieties (it means a half or portion/share/part) for PET imaging during off-production hours. This will, in turn, attract the collaboration of an elite group of researchers, foster discovery and publications, and lead to the commercialization of new specific disease targeting products.

However, to achieve this goal the cyclotron must be within close proximity to the PET imaging facilities (currently located on the ground floor). Carbon-11 has a half-life of 20.3 minutes. That is, half of the produced radioactivity disappears every 20.3 minutes (1/2 after 20.3 minutes, ¼ after 40.6 minutes etc.). Its production, incorporation into the moieties under research, its injection into patients, and image acquisition must be accomplished within less than 2 to 3 half lives to obtain useful biodistribution data of the molecules under investigation.

The proposed PET Radiopharmacy will consist of a cyclotron and GMP compliant production laboratories.

The major market for PET is currently in the diagnosis and staging of cancer patients. In particular, lung, colon, breast, cervical, prostate, head and neck, lymphoma, melanoma, and oesophageal cancers are the prime diagnostic targets. The primary targeting radiopharmaceutical currently used is a radiolabelled glucose called Fluoro-Deoxy Glucose (FDG) and the attached radiolabel is Fluorine-18. The growth of PET procedures is expected to continue. Although the prominent focus of PET is still oncology, applications in cardiology and neurology are increasing.

Since FDG is a radiopharmaceutical, its production must be compliant with the related Therapeutic Goods Administration (TGA) requirements for Good Manufacturing Practice (GMP).

New PET radiopharmaceuticals and molecular targeting agents that will measure biochemical processes to assess patient response to therapy by measuring cellular response to therapy rather than metabolism are under investigation and in the pipeline. Their commercialization will aid in the treatment, monitoring and therapy planning for breast cancer, prostate cancer, brain cancer, bone cancer and other common cancers. Furthermore, as the availability of PET increases and its capabilities become more viable to referring physicians, its applications in oncology, cardiology, and neurology are also expected to increase.

Cyclotron

The Cyclotron is an electric/electronic device used to manufacture the radiolabel – Fluorine-18. This is achieved by introducing into the device hydrogen atoms which are then accelerated to a very high

velocity using high frequency (radio frequency) electrical fields along an increasing circular path in a very high vacuum. The accelerated hydrogen atoms are then extracted from the device and made to impinge on a special target of Oxygen to produce the Fluorine-18. Placing the device within a concrete enclosure provides sufficient shielding to protect the operator. The Fluorine-18 is then transported to the GMP-compliant production laboratory where it is incorporated into the Deoxy Glucose molecule to make FDG. The finished product is assessed for quality and sterility in the quality control laboratory prior to shipment to the end user.

Functional Requirements
The spatial relationships are critical in the planning of the Unit to ensure that functionality is achieved and occupational health and safety issues are met.

A Cyclotron is proposed and this will require a “bunker” with concrete walls and ceiling of approximately 2.1 m thick. The clear floor to ceiling measurement should be no less than 2.7 m.

An anti room or technical room is required adjacent to the Cyclotron room to accommodate equipment and to allow for the removal of the entrance “block”. This space should be accessible for the removal, if necessary, of the Cyclotron in the future.

The quality control and production rooms should be adjacent to the Cyclotron and the store should be adjacent to the production room.

Access into the store room and production should be via airlocks.

Airlock access is also required to enter the Unit and to access the packing and dispatch area.

Office Accommodation is required for up to 4 persons.

Two laboratory spaces (hot cells, GMP) are required for further quality control and research and development purposes (perhaps a third laboratory space is required for the production of Carbon II).

To operate the PET Radiopharmacy will require 150A 3 phase 50 Hz standard power supply at a minimum. The installation of a transformer may vary depending on each cyclotron manufacturer’s specifications.

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