



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

STANDARD APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number: #08-17

Applicant: Kuakini Medical Center
347 N. Kuakini Street
Honolulu, Hawaii 96817

Phone: 808-547-9231

Project Title: Establishment of PET/CT scanner service

Project Address: same

1. TYPE OF ORGANIZATION: (Please check all applicable)

- Public _____
- Private X
- Non-profit X
- For-profit _____
- Individual _____
- Corporation X
- Partnership _____
- Limited Liability Corporation (LLC) _____
- Limited Liability Partnership (LLP) _____
- Other: _____

NOV -5 19:31

2. PROJECT LOCATION INFORMATION

A. Primary Service Area(s) of Project: (please check all applicable)

- Statewide: _____
- O`ahu-wide: X
- Honolulu: _____
- Windward O`ahu: _____
- West O`ahu: _____
- Maui County: _____
- Kaua`i County: _____
- Hawai`i County:- _____

3. DOCUMENTATION (Please attach the following to your application form):

A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)

PET/CT Scanner Services to be established on the Kuakini Medical Center campus.

B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)

None.

C. Your governing body: list by names, titles and address/phone numbers

See Attachment B – List of Board of Directors of Kuakini Medical Center

D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:

- Articles of Incorporation
- By-Laws
- Partnership Agreements
- Tax Key Number (project's location)

See Attachment C – Copy of Kuakini Medical Center's Amended and Restated Articles of Incorporation; copy of Kuakini Medical Center's Restated Bylaws; and Tax Key Number of proposed project location

4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "x" in the appropriate box.

	Used Medical Equipment (over \$400,000)	New/Upgraded Medical Equip. (over \$1 million)	Other Capital Project (over \$4 million)	Change in Ownership	Change in Service/Establish New Service/Facility	Change in Beds
Inpatient Facility		X			X	
Outpatient Facility						
Private Practice						

5. **TOTAL CAPITAL COST:** \$2,154,100

6. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
TOTAL	---	---	---

Not applicable – there are no bed changes resulting from Kuakini’s proposed project.

7. **CHANGE OF SERVICE:** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please reference the Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

Kuakini's proposed project to establish a PET/CT scanner service will result in the addition of a new service which is a Positron Emission Tomography (PET) / Computerized Tomography (CT) imaging service on the Kuakini Medical Center campus.

NOV -5 4:59:31

8. PROJECT COSTS AND SOURCES OF FUNDS (For Capital Items Only)

A. List All Project Costs:	AMOUNT:
1. Land Acquisition	_____
2. Construction Contract	\$ 200,000
3. Fixed Equipment	\$ 1,954,100
4. Movable Equipment	_____
5. Financing Costs	_____
6. Fair Market Value of assets acquired by lease, rent, donation, etc.	_____
7. Other: _____	_____
TOTAL PROJECT COST:	\$ 2,154,100

B. Source and Method of Estimation

Describe how the cost estimates in Item "A" were made, including information and methods used:

The cost estimates are based on a cost projection for the minor renovation of existing facility space to install the combined PET/CT scanner and the equipment purchase agreement for the combined PET/CT scanner (See Attachment A – Copy of purchase agreement from General Electric for a combined PET/CT scanner).

C. Source of Funds	AMOUNT:
1. Cash	\$ 2,154,100
2. State Appropriations	_____
3. Other Grants	_____
4. Fund Drive	_____
5. Debt	_____
6. Other: _____	_____
TOTAL SOURCE OF FUNDS:	\$ 2,154,100

9. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

a) Date of site control for the proposed project,

Not Applicable. The proposed combined PET/CT scanner will be located in the existing facilities of Kuakini's Imaging Department at the Medical Center.

b) Dates by which other government approvals/permits will be applied for and received,

Upon approval of CON, Kuakini will apply for other government approvals/permits as required.

c) Dates by which financing is assured for the project,

Financing for the Kuakini's project is already secured.

d) Date construction will commence,

Upon approval of CON, Kuakini will begin renovation of an existing room in the Imaging Department for the installation of the combined PET/CT scanner.

e) Length of construction period,

Maximum construction period for the required renovation work is three (3) months.

f) Date of completion of the project, and

June 2009

g) Date of commencement of operation.

July 2009

10. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

- a) Relationship to the Hawai'i Health Performance Plan (H2P2), also known as the State of Hawai'i Health Services and Facilities Plan.
- b) Need and Accessibility
- c) Quality of Service/Care
- d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
- e) Relationship to the Existing Health Care System
- f) Availability of Resources

2008 NOV -5 4:29 31

Executive Summary

Kuakini Medical Center (Kuakini) has recognized that the incidence of cancer is projected to increase both nationally and locally in the future years as the baby boomers age-up and will comprise a larger percentage of the elderly population. The growth in the elderly population is expected to increase the demand for health care services including outpatient services.

Population growth in Hawaii is projected to increase by 22% between 2000 and 2025, the largest population growth will be in the elderly age group (ages 65 and older) as this group is estimated to increase by approximately 90% between 2000 and 2025 (*DBEDT "Population and Economic Projections for the State of Hawaii to 2025," February 2000*).

In relation to the population growth, newly diagnosed cancer cases are expected to increase by 23% in the next decade, with the largest portion of the increase represented by the Medicare-eligible population (*National Cancer Institute projections*).

While cancer prevention and cure are still out of reach for most tumor sites, cancer patients have experienced increasing survival rates due to early interventions taken for medical conditions and their disease. Average five-year survival rates have increased from 50 to 63 percent over the last 25 years. Prostate cancer in particular has reflected an increasing survival rate of nearly 100 percent due to the advances in cancer screening. As a result, the number of people living with cancer and requiring medical care will continue to rise, and will increase the future demand for health care services (*Health Care Advisory Board, "Future of Oncology Service Line Innovation Brief-2004"*).

Cancer services are one of Kuakini's major clinical strengths and will continue as one of the service priorities for the future. Kuakini provides all three major modalities for cancer treatment: -- surgical oncology; medical oncology; and radiation therapy. Also Kuakini has been involved since the mid-1960's in a longstanding federally funded cancer research project, the Kuakini Japan-Hawaii Cancer Study (which is an adjunct project to the Kuakini Honolulu Heart Program longitudinal study), as well as other federally funded and privately funded health related research projects.

Kuakini has determined that there is a need in the Oahu community and the State of Hawaii for the availability of an additional combined PET/CT scanners in the hospital setting for purposes of diagnosis and screening, therapy planning, monitoring of treatment, and continuing of research initiatives related to cancer patients and other types of patients.

The clinical PET market is rapidly migrating toward the configuration of hybrid scanners that combine PET and CT imaging capabilities. Today, the vast majority of PET scanners sold in the U.S. are hybrid or combined PET/CT imaging equipment, which reflects the rapid shift of clinical consensus from depending on computer software fusion (i.e. to merge PET and CT images by computer applications) to composite modalities whereby the PET and CT scanners are mounted together on the same frame (*Health Care Advisory Board, "Future of Oncology Service Line Innovation Brief-2004"*)

Kuakini has determined that the General Electric (GE) Discovery ST PET/CT system is the equipment that will provide the best value to Kuakini and its patients. Kuakini's current multi-slice CT scanner and CT simulator for radiation therapy are both GE equipment.

Kuakini has identified the following benefits of acquiring a combined PET/CT imaging equipment.

- The PET/CT will become an integral part of the entire cancer management and treatment process for Kuakini's patients.

- The PET/CT offers extensive possibilities for improving the diagnosis and staging of tumors, identification and localization of disseminated diseases, radiation therapy treatment planning, and monitoring the effects of chemotherapy and radiation therapy.
- The PET/CT will help reduce unnecessary biopsies and surgeries of cancer patients.
- The PET/CT will improve the localization of dead or diseased tissues and help refine the clinical course of treatment for both cardiac and neurology patients.
- The PET/CT will provide increased diagnostic capabilities for patients, and patients will avoid undergoing two examinations performed on separate PET and CT equipment.
- The PET/CT has throughput scan times that are 60% shorter than a separate standalone PET scanner.
- Most radiologists and oncologists agree that the combined PET/CT scan technology is clinically superior as well as easier to use (*Health Care Advisory Board, "Future of Oncology Service Line Innovation Brief-2004"*).
- The PET/CT will strengthen Kuakini's diagnostic imaging service for its inpatients and outpatients.
- The PET/CT will be purchased from General Electric (GE) and will provide operational efficiencies since Kuakini's current multi-slice CT scanner is from GE, and the training of imaging technologists will be faster.
- The PET/CT will be instrumental in gathering detailed metabolic and morphological data on current and future participants of Kuakini's research cohort who volunteer in Kuakini's longitudinal research projects.
- Currently, Kuakini purchases PET imaging services from The Queen's Medical Center for one of Kuakini's research projects on aging that is federally funded by the National Institute on Aging.
- The PET/CT will enhance Kuakini's delivery of health care services and enhance the value that Kuakini provides to the community it serves.

In addition to providing high-quality, and cost-effective health care services, Kuakini has received international and national recognition for its 40+ years of epidemiological and biomedical research. Over 500 scientific publications and presentations regarding cardiovascular disease, stroke, aging, cancer, dementia, Alzheimer's disease, Parkinson's disease, and related genetics research have been produced. Research subjects and their families have directly benefited from their participation in the research projects through the study findings and receiving free clinical examinations.

Since 1965, the National Institutes of Health (NIH) has provided funding support for the Kuakini Honolulu Heart Program (HHP) and its longitudinal study of 8,006 men of Japanese ancestry born between 1900 and 1919 and were veterans. Numerous ancillary studies have also been conducted, with several involving collaborations with researchers from Japan and U.S. mainland universities and health care organizations. The Kuakini HHP, and its corollary studies (including the Kuakini Honolulu-Asia Aging Study), continue to receive NIH support for the ongoing study of the surviving 1,000 research participants, the family members of the research participants for multi-generational studies,

and the stored specimens of the research participants. To-date, the research programs sponsored by Kuakini have received over \$70 million in federal research funding.

The life expectancy of the surviving Kuakini research participants is anticipated to be approximately five to seven years, and therefore, Kuakini is planning to perform combined PET/CT scanning on these remaining research participants for the purpose of adding to the research database. Also, Kuakini is initiating multi-generational examinations for the offspring of the Kuakini HHP participants in order to obtain research data to review the changes between (as well as within) generations, and this will include performing combined PET/CT scanning for these multi-generational participants. There are also plans to continue examinations of the Kuakini Japan-Hawaii Cancer Study (JHCS) research participants who do not overlap with the Kuakini HHP participants, as well as conducting multi-generational examinations for these Kuakini JHCS participants. Another area of research will be the use of the combined PET/CT modality in collaborative research initiatives between Kuakini and specific research centers in Japan to conduct comparative population research studies using the same type and model of diagnostic imaging equipment including the GE combined PET/CT.

There is also tremendous potential research-related value in using the combined PET/CT scanner in research studies on Alzheimer's disease, Parkinson's disease, dementia, and aging.

Relationship to the Hawai'i Health Performance Plan (H2P2)

Kuakini's proposed project to establish a PET/CT scanner service directly supports the overall goals of the Hawai'i Health Performance Plan (H2P2) as stated in Chapter 2, page 11-1, Section C. 1:

"The Hawaii Health Performance Plan draws on the goals of national and local efforts ... these are integrated community specific concerns as well as age-group sub-goals ... increase the span of healthy life for Hawaii's residents ... older adults will maintain good health and independent personal functioning ... reduce health disparities among Hawaii residents ... achieve equitable and effective access at reasonable cost for all Hawaii's residents to health services that are responsible to the holistic needs of community's members ... "

Kuakini's proposed project addresses the critical elements of a health care delivery system outlined in Section F of the H2P2 Chapter II, Vision and Guiding Principles. Also, Kuakini's proposed project will greatly improve the availability and access to combined PET/CT imaging services in the community and improve the availability of this modality for research applications, if approved. Availability and access to this diagnostic imaging modality will be improved since Kuakini's acquisition of a combined PET/CT scanner will be the third in the State of Hawaii and the second combined PET/CT scanner to be operated in an acute hospital setting. The Queen's Medical Center is the first acute hospital in Hawaii with a combined PET/CT scanner. The other existing combined PET/CT scanner is operated by Hawaii PET Imaging, a private freestanding imaging center located at Restaurant Row. There is one separate or standalone PET scanner (i.e. not a combined PET/CT scanner) in Hawaii, which is a 10-year old equipment serving as a backup scanner at The Queen's Medical Center.

Kuakini's proposed project also supports the H2P2 focus and concern on cancer as noted in Chapter V of the H2P2. The benefits of the combined PET/CT scanner as described in this application will greatly improve Kuakini's diagnostic imaging capabilities (including early detection), therapy planning, monitoring the effects of treatment, and continuing research related studies on cancer and other diseases. Research findings have shown that the earlier cancer is diagnosed and treated, the chances for survival and having a better quality of life increases.

Need and Accessibility

Both the U.S. and Hawaii are projected to experience continuing growth in the population and an increase in the elderly population as a percentage of the total population. These projections are expected to result in an increased demand for and the utilization of health care services including the diagnostic imaging services that are provided at Kuakini and other health care facilities.

Population growth in Hawaii is projected to increase by 22% between 2000 and 2025. The largest population growth will be in the elderly age group (persons 65 years and older) as this group is estimated to increase by approximately 90% between 2000 and 2025 (*DBEDT, "Population and Economic Projection for the State of Hawaii to 2025," [February 2000]*).

In relation to the population growth, newly diagnosed cancer cases are expected to increase by 23% in the next decade, with the largest portion of the increase represented by the Medicare-eligible populations (*National Cancer Institute*).

Since Kuakini's customer and payor mix is predominantly the elderly and Medicare eligible beneficiaries (approximately 70% of Kuakini's inpatient admissions are Medicare eligible beneficiaries), and Kuakini's future plans are to continue its longitudinal research projects, Kuakini believes that it is medically appropriate as a tertiary acute care hospital with a large elderly patient population and from a research perspective to propose the establishment of a PET/CT scanner service in order to meet the needs of the community.

Currently, Kuakini has no utilization data for a PET/CT scanner service since this is not an existing service at Kuakini. A projection of the utilization for the proposed PET/CT scanner service is reflected in Table A, under Section B: Need and Accessibility, subsection F. Types of Patients and Sources of Funds. Kuakini projects that the utilization of its proposed PET/CT scanner service will be at the annual capacity threshold of a minimum average annual utilization of 1,000 PET procedures per year (as indicated in H2P2) by the third year of operations of Kuakini's new service.

The establishment of a PET/CT scanner service at Kuakini will increase the availability and access to state-of-the-art diagnostic imaging technology for the Hawaii community as well as allow the distribution of Kuakini's current CT caseload between the existing multi-slice CT scanner and the CT of the proposed combined PET/CT scanner.

Quality of Service/Care

The combined PET/CT scanner will result in (1) the community having increased access to state-of-the-art diagnostic imaging technology for improved diagnostic services and clinical outcomes for detection and treatment of cancer and other health conditions, (2) increased opportunities for expanded research studies (funded by the federal agencies, private foundations, and Kuakini), and (3) improved delivery of health care services and improvements to the health status of the community.

Kuakini Medical Center is (1) fully accredited by the Joint Commission, an accrediting organization for acute care hospitals (Kuakini's most recent survey was conducted in May 2008), (2) licensed as an acute care hospital through the Hawaii State Department of Health, and (3) certified to provide acute hospital services by the Centers for Medicare and Medicaid Services (CMS). Kuakini's Imaging Department (which encompasses Radiology and Nuclear Medicine Services) adheres to the licensing standards and guidelines developed by the American College of Radiology, Society of Nuclear Medicine, Nuclear Regulatory Commission, and the Food and Drug Administration.

Cost and Finances

Kuakini's proposed establishment of a PET/CT scanner service will have a minimal impact on the overall costs of health care services for the Hawaii community as it will be funded by Kuakini's available capital resources. The total capital cost for the proposed project is \$2,154,100. Kuakini's proposed project will be cost-effective as it will (1) utilize existing facility space currently occupied by the CT simulator for radiation therapy; (2) utilize current imaging staff in Kuakini's Imaging Department, and (3) utilize radioactive isotopes which will be purchased from The Queen's Medical Center as Kuakini has no plans to duplicate the cyclotron services already provided by Queen's.

In terms of ongoing costs and reimbursement, the combined PET/CT scanner will provide relief to Kuakini's existing multi-slice CT scanner by serving as the backup CT and also allow for the balancing of the caseload between the two CT scanners.

Kuakini's proposed establishment of a PET/CT scanner service will also replace part of the procedures performed on Kuakini's existing nuclear medicine equipment, and thereby allow Kuakini to phase-out the older nuclear medicine equipment which are not as effective.

According to the *Health Care Advisory Board, "Future Oncology Service Line Innovation Brief-2004,"* current PET/CT reimbursement levels enable hospitals to break-even by performing approximately 2.2 scans per day. Kuakini is projecting a minimum utilization of 2.2 scans per day (based on a 5-day week operating schedule) and this translates to a projected 11 scans/procedures per week for the combined PET/CT scanner in the first year of operations.

Relationship to the Existing Health Care System

Kuakini's proposed project will meet the needs of its patient population (both for inpatient and outpatient services) and the needs of the community served by Kuakini through its initiatives for ongoing biomedical and epidemiological research. The proposed project is consistent with Kuakini's **Mission** to improve the health status of the community it serves by:

- providing comprehensive health care services and programs at reasonable cost;
- continuously improving the quality of health care services and programs;
- encouraging clinical research;
- supporting training and education programs for health care personnel; and
- offering community service programs.

The proposed project also exemplifies Kuakini's **Core Values** of:

Quality:	Commitment to excellence
Caring:	Concern for the well-being of people and human values
Ownership:	Kuakini's viability is everyone's responsibility; stewardship
Pride:	Taking personal pride in our work actions
Teamwork:	Support the Kuakini Health Care Team to achieve positive results and quality outcomes
Respect:	Treating people with dignity, fairness, and courtesy
Responsibility:	Being accountable for our work and actions

98 NOV -5 4:26

Availability of Resources

The total cost of the proposed project will be financed by Kuakini Medical Center through its available capital resources.

The radioactive isotopes required for PET imaging at Kuakini will be produced by the cyclotron operated by The Queen's Medical Center (QMC). Kuakini has had discussions with QMC regarding a written agreement for the purchase of radioactive isotopes from QMC.

Kuakini last purchased radioactive isotopes from QMC in April 2004 in order to perform PET-like diagnostic imaging services at Kuakini using a PET-MCD imaging equipment in nuclear medicine, which was a modified gantry mounted gamma camera with a molecular-coincidence detection system that used radioactive isotopes. The radioactive isotope 18-Fluorine was incorporated in a form of glucose to form 18-F-fluorodeoxyglucose or FDG. The metabolites from FDG accumulate in tissues with high metabolic activity such as tumors.

The existing imaging staff of Kuakini's Imaging Department will be utilized for the operations of the proposed PET/CT scanner service. Other related services will be contracted by Kuakini from external organizations as necessary.

08 NOV -5 19:32