



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

LINDA LINGLE
GOVERNOR

MARILYN A. MATSUNAGA
ADMINISTRATOR

1177 Alakea St. #402, Honolulu, HI 96813 Phone: 587-0788 Fax: 587-0783 www.shpda.org

June 6, 2003

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 03-04
Hawaii Radiologic Associates, Ltd.)	
)	
Applicant)	
_____)	DECISION ON THE MERITS

DECISION ON THE MERITS

The State Health Planning and Development Agency (hereinafter "Agency"), having taken into consideration all of the records pertaining to Certificate of Need Application No. 03-04 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Hawaii County Subarea Health Planning Council and the Certificate of Need Review Panel, hereby makes its Decision on the Merits, including findings of fact, conclusions of law, order, and written notice on Certificate of Need Application No. 03-04.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of a stationary 0.7 Tesla, open Magnetic Resonance Imaging (MRI) service at Suite 115, 670 Ponahawai Street, Hilo, HI at a capital cost of \$2,000,000.
2. The applicant is a professional corporation formed pursuant to the laws of the State of Hawaii.

3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).

4. On February 28, 2003, the applicant filed with the Agency a Certificate of Need application for the establishment of a stationary 0.7 Tesla, open MRI service at Suite 115, 670 Ponahawai Street, Hilo, HI at a capital cost of \$2,000,000. (the "Proposal") On March 10, 2003, the Agency determined that the application was incomplete and requested additional information. On March 24, 2003 and March 28, 2003, the applicant submitted additional information. On March 28, 2003 the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #03-04.

5. The period for Agency review of the application commenced on May 1, 2003, the day notice was provided to the public pursuant to 11-186-39 HAR.

6. The Hawaii County Subarea Health Planning Council met at a public meeting on May 7, 2003 and recommended approval of this application by a vote of 6 in favor and none opposed.

7. The application was reviewed by the Certificate of Need Review Panel ("Panel") at a public meeting on May 16, 2003. The Panel recommended approval of the Proposal by a vote of 6 in favor and none opposed.

8. The Statewide Health Coordinating Council review of the application was waived pursuant to Section 323D-44.6 HRS.

9. This application was reviewed in accordance with Section 11-186-15, HAR:

"(a) The agency shall consider the following criteria in the review of an application for a certificate of need:

- (1) The need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, are likely to have access to those services;
- (2) In the case of reduction or elimination of a service, including the relocation of a facility or service:
 - (A) The need that the population presently served has for the service;
 - (B) The extent to which that need will be met adequately by the proposed relocation or by alternative arrangements; and
 - (C) The effect of the reduction, elimination, or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, to obtain needed health care;

- (3) The probable impact of the proposal on the overall costs of health services to the community;
- (4) The probable impact of the proposal on the costs of and charges for providing health services by the applicant;
- (5) The immediate and long term financial feasibility of the proposal;
- (6) The applicant's compliance with federal and state licensure and certification requirements;
- (7) The quality of the health care services proposed;
- (8) In the case of existing health care services or facilities, the quality of care provided by those facilities in the past;
- (9) The relationship of the proposal to the state health services and facilities plan and the annual implementation plan;
- (10) The relationship of the proposal to the existing health care system of the area;
- (11) The availability of less costly or more effective alternative methods of providing service;
- (12) The availability of resources (including health personnel, management personnel, and funds for capital operating needs) for the provision of the services proposed to be provided and the need for alternative uses of these resources as identified by the state health services and facilities plan and the annual implementation plan.

(b) Criteria for review of an application may vary according to the purpose for which particular review is being conducted or according to the type of health care service being reviewed."

10. Pursuant to Section 323D-43(b), HRS:

"(b) No Certificate shall be issued unless the Agency has determined that:

- (1) There is a public need for the facility or service; and
- (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs."

11. Burden of proof. Section 11-186-42, HAR, provides:

"The applicant for a certificate of need or for an exemption from certificate of need requirements shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence."

II

FINDINGS OF FACT

A. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE STATE PLAN (H2P2)

Vision and Guiding Principles (Chapter II)

12. In relation to the goals and objectives of H2P2, the applicant states at page A-2 of its application:

"The increased accessibility of this service will reduce the need for other less appropriate tests and procedures (including invasive procedures) and/or multiple tests and procedures. These tests may be more costly...and less accurate. For example, MRI is the diagnostic study of choice in elderly patients with hip fractures who are osteoporotic and whose x-rays are negative. Additionally the College of Radiology's appropriateness criteria clearly establish MRI as the preferred procedure for seizures, low back pain, screening for cerebral aneurysms, stress fractures and demensia. In these cases, the objective of "reducing morbidity and pain through timely and appropriate treatment" will be met."

13. In relation to the H2P2 basic principals of the health care delivery system, the applicant states that its proposal will make the health care delivery system well coordinated and responsive to community/regional needs by functioning as a "back up" unit to the busiest MRI on the Big Island at Hilo Medical Center (HMC).

14. With respect to the H2P2 desired characteristic of supporting collaboration between health care providers, the applicant states at page A-5 of its application:

"HRA (Hawaii Radiologic Associates) plans to continue to collaborate with the regional and tertiary hospitals. HRA understands that some patients require hospital care and HRA does not intend to undermine hospital based radiological services."

15. In relation to the H2P2 capacity thresholds for MRI services, the applicant states that for a new MRI unit, there is a minimum threshold of 1,500 procedures per year for all providers in the service area and that the proposed unit should meet the minimum threshold by its third year of operations.

16. The applicant states that in 2002, HMC performed approximately 3,360 MRI procedures and North Hawaii Community Hospital (NHCH) performed approximately 2,504 MRI procedures

17. The applicant states that Kona Community Hospital (KCH) established its MRI service in July of 2002 and performed over 1400 procedures in its first 10 months of operations. The applicant projects that, based upon this utilization, KCH will exceed the minimum threshold of 1500 procedures by the end of its first 12 months of operations.

18. The applicant projects that it will perform 1,771 procedures in Year 2 of its Proposal.

Diseases and Conditions (Chapters IV-XI)

19. The applicant states that, "The areas that MRI services will provide the most significant impact include cancer, diabetes, heart disease, stroke, dental (oral) health, preventable injuries and violence."

20. The applicant states, "...with the ability of MRI to differentiate between soft tissue and bony matter, it will assist with the detection of a variety of cancers and can be used on most body parts."

21. The applicant further states that, "MRI services will also be used during the cancer treatment phase to detect changes in the cancer as treatment progresses."

22. The applicant states that, "...MRIs will be used for cardiovascular imaging, which can assist in the detection and prevention of cardiac conditions. For example, MRIs may be used to assist with the detection of blocked vessels that could lead to heart attacks and stroke."

23. The Agency finds that this criterion has been met.

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

24. The applicant states that in 2002, HMC performed approximately 3,360 MRI procedures and North Hawaii Community Hospital (NHCH) performed approximately 2,504 MRI procedures.

25. The applicant states that Kona Community Hospital (KCH) established its MRI service in July of 2002 and performed over 1400 procedures in its first 10 months of operations. The applicant projects that based upon this utilization, KCH will exceed the minimum threshold of 1500 procedures by the end of its first 12 months of operations.

26. The applicant projects that it will perform 1,771 procedures in Year 2 of its Proposal.

27. The applicant states that the average annual growth in MRI procedures per 1000 persons for Hawaii County from 1997 to 2001 inclusive was 18.86%.

28. The applicant estimates that using the 18.86% annual growth rate and based upon the population projections from the Hawaii State Department of Business, Economic Development and Tourism, the projected five year MRI utilization in Hawaii County from 2002 to 2006 inclusive would be: 6363, 7671, 9239, 11155 and 13473 procedures respectively.

29. The applicant projects that it will perform 506 MRI procedures from September through December 2003 (assuming operations commence in September of 2003), 1,771 procedures in 2004 and 2,024 procedures in 2005. The applicant states that all existing units will remain above the H2P2 threshold.

30. In a memorandum dated May 14, 2003, Juliette Tulang, Chair, Hawaii County Subarea Health Planning Council forwarded the Council's recommendation for approval of this application. The recommendation states in pertinent part:

"The applicant has shown that there is a need for the proposed services. All other providers in the service area are meeting the H2P2 threshold and based on historical projections, the applicant projects that it will achieve the threshold in the second year of operation."

31. The applicant states that its services "will be accessible to all patients who need outpatient MRI services. Services will be provided without discrimination based on race, ethnicity, income, religion, gender or any other category."

32. The Agency finds that the need and access criteria have been met.

C. REGARDING QUALITY AND LICENSURE CRITERIA

33. The applicant states that it has provided general outpatient radiology and ultrasound services in Hilo since 1972, in Kona since 1992 and at its Hilo Women's Imaging Center since 1999.
34. The applicant states that it will follow the MRI guidelines in the American College of Radiology standards and will seek ACR accreditation for the unit after installation.
35. The applicant states that all radiologists will be licensed in the State of Hawaii and certified by the American Board of Radiology.
36. The applicant states that MRI technologists will be certified by the American Registry of Radiologic Technologists with an additional certification as an MRI technologist with appropriate state licensure.
37. The applicant states that all radiologists will be expected to meet or exceed all state and national registry requirements for continuing medical education.
38. The Agency finds that quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

39. The applicant states that the project will keep overall health care costs down by decreasing the utilization of less optimal diagnostic techniques and performing procedures on an open MRI which costs less than operating a high field unit.
40. The applicant states at page A-2 of its application:

"The increased accessibility of this service will reduce the need for other less appropriate tests and procedures (including invasive procedures) and/or multiple tests and procedures."
41. With respect to the financial feasibility of the Proposal, the applicant projects that, in Exhibit D-2 of its application, the excess funds from operations (after payment of principal and interest on the debt associated with the purchase of the MRI equipment) will be (\$30,145) in year one and \$203,039 in year three of the Proposal.

42. In her memorandum dated May 14, 2003 forwarding the Hawaii County Subarea Health Planning Council's recommendation for approval of this application, Juliette Tulang states: "Based upon the information provided by the applicant, the proposal is financially feasible."

43. The Agency finds that cost and financial criteria have been met.

E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA

44. The applicant states that there should be little or no impact on the existing MRI units and that all existing units will remain above the H2P2 threshold.

45. In her memorandum dated May 14, 2003 forwarding the Hawaii County Subarea Health Planning Council's recommendation for approval of this application, Juliette Tulang states:

"The applicant has a professional relationship with Hilo Medical Center for radiological services and states that this relationship is expected to continue with the proposed service."

46. The applicant states at page E-3 of its application:

"Currently, HRA is in discussion with HMC to enter into a joint venture (the 'MRI Joint Venture') for the purpose of jointly owning and operating the proposed open MRI system. HMC has advised HRA that HMC will not be in a position to immediately enter into the MRI Joint Venture as the business arrangement must be approved through several layers of corporate governance. Accordingly, in order to provide HMC the opportunity to participate in the MRI Joint Venture when it has received all the necessary corporate approvals, HRA is willing to provide an option to HMC to acquire up to 25% of the ownership interest in the MRI Joint Venture which will be a limited liability company to be formed under the name 'HRA Magnetic Resonance Imaging, LLC.' HRA has provided to HMC for its review a document entitled 'Rights Agreement' evidencing the option to be granted to HMC. The parties are currently in the process of negotiating the Rights Agreement.

Under the Rights Agreement, HMC will have the opportunity for a period of one year following the effective date of the Rights Agreement to exercise its right to acquire up to 25% of the ownership interest in the HRA Magnetic Resonance Imaging, LLC for a purchase price equal to the proportionate share of the capital contributions.

In this manner, regardless of whether HMC will ultimately choose to become a participant in the MRI Joint Venture, HRA will immediately initiate and implement the necessary steps for acquiring and operating the proposed MRI system. Because of this and because the LLC, which has not yet been formed, will be owned either wholly or primarily (75% or more) by HRA, HRA is the applicant on this CON Application."

47. In his public testimony at the Hawaii County Subarea Health Planning Council meeting May 7, 2003, Ronald Schurra, CEO, Hilo Medical Center, stated that although HMC has been trying to come together with HRA for nearly two years on this project, "substantial economic problems" at HMC and a "high level of emotion" associated with this issue has led to the point where they couldn't come together until the last six months.

48. In his public testimony at the Hawaii County Subarea Health Planning Council meeting May 7, 2003, David Camacho, Vice President, Hawaii Radiologic Associates, Ltd. stated that HRA has been trying to proceed with the joint venture but the corporate governance delays at HMC have delayed the joint venture. Accordingly, Mr. Camacho stated that in order to respond to the immediate MRI needs of the community, it has proceeded with the project now and has offered HMC the option to acquire an interest in the MRI Joint Venture once HMC has received all the necessary corporate approvals. Mr. Camacho stated that under the terms of the Rights Agreement, HMC would have up to a year to enter into the joint venture.

49. Ron Schurra stated that he would seek a resolution from his board of directors at their May 8, 2003 board meeting to authorize HMC, to the extent possible, to explore a joint venture or other legal arrangement which would allow HMC and HMA to work together on this project.

50. In a letter to the Agency dated May 14, 2003, the applicant states:

"...when HRA's open MRI unit becomes operational, it will be available as a back-up to Hilo Medical Center's closed MRI unit in times the hospital's unit is unavailable due to repair, maintenance, or any other reason. We are also willing to provide back-up services with respect to the open MRI unit as necessary to treat the hospital's patients in case of emergency or to handle overflow capacity. We are willing to enter into an agreement with Hilo Medical Center to provide back-up services."

51. The Agency finds that this criterion has been met.

F. REGARDING THE AVAILABILITY OF RESOURCES

52. With respect to personnel resources, the applicant states its Proposal will require the following: 0.75 – 1 FTE Radiologist, 1.5 FTE MRI technologists, and 1 FTE Clerk/Receptionist. The applicant states that it presently employs 34 technologists and 36 ancillary personnel and maintains an ongoing recruiting program from which the positions for the Proposal will be filled without difficulty.

53. In her memorandum dated May 14, 2003 forwarding the Hawaii County Subarea Health Planning Council's recommendation for approval of this application, Juliette Tulang states:

"The financial and personnel resources are available for the proposal. The applicant stated that currently, while MRI technicians are scarce and are generally recruited from the mainland, the applicant is starting a technology school on the Big Island to address the projected long term need for this type of personnel."

54. With respect to financial resources, the applicant states that equipment cost for the project is \$1,500,000 and the cost of construction is \$500,000. The applicant states that both Central Pacific Bank and Bank of Hawaii have approved loans for the total project cost of \$2,000,000.

55. The Agency finds that the applicant has met this criterion.

III

CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 03-04 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Hawaii County Subarea Health Planning Council and Certificate of Review Panel, and based upon the findings of fact contained herein, the Agency concludes as follows:

The applicant has met the requisite burden of proof and has shown by a preponderance of the evidence that the Proposal meets the criteria established in Section 11-186-15, HAR.

Accordingly, the Agency hereby determines that, pursuant to Chapter 323D-43(b):

- (1) There is a public need for this proposal; and
- (2) The cost of the proposal will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

ORDER

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a certificate of need to Hawaii Radiologic Associates, Ltd. for the proposal described in Certificate Application No. 03-04. The maximum capital expenditure allowed under this approval is \$2,000,000.

WRITTEN NOTICE

Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 of the Agency's Certificate of Need Program rules. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

DATED: June 6, 2003
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY

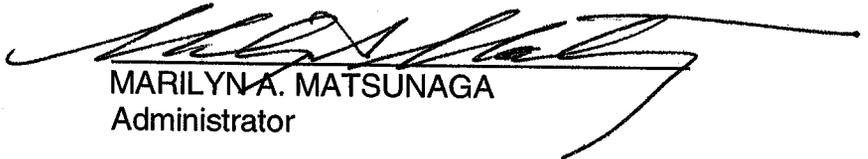

MARILYN A. MATSUNAGA
Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Decision on the Merits, including findings of fact, conclusions of law, order, and written notice, was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on June 6, 2003.

Scott Grosskreutz, M.D.
President
Hawaii Radiologic Associates, Ltd.
688 Kinoole St., Suite 103
Hilo, Hawaii 96720

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY


MARILYN A. MATSUNAGA
Administrator