SAINT JOSEPH MERCY HEALTH SYSTEM
A MEMBER OF TRINITY HEALTH

St. Joseph Mercy Hospital
Radiation Safety Office
5301 E. Huron River Dr.
Ann Arbor, MI 48103-0995
Phone: 734 712-8746
Fax: 734 712-1369

Fax

TO: Colleen Casey
U.S. Nuclear Regulatory Comm
Region III
ATTN: Materials Licensing

From: Ralph P. Lieto, MSE,
Radiation Safety Officer

Fax: 630-515-1078 **Date:** September 13, 2007

Phone: **Pages (inc. cover page):** 7

Re: License No.: 21-00943-03 Control No.: 316316

☑ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☑ **Please Process**

We are responding to the comments and questions in your fax of August 24, 2007 regarding the training and experience of Samir Narayan, MD to be listed as an authorized user on our NRC license.

NRC Comment 1. The list provided by UC-Davis dated June 1. 2007, attached to your letter dated June 8., 2007, only states "names, expiration dates, category and training exempt"- no specific information, no degrees, no dates of authorization, no modalities of use authorized, etc. are given to corroborate the information in your letter dated June 8, 2007.
Please submit a currently signed and dated letter from the Chairperson of the RSC for UC-Davis stating Dr. Narayan's name and degree, his dates of authorization, the specific modalities he was authorized for (as correlated to sections of 10 CFR Part 35) and, as appropriate, any other information that will enable us to evaluate his qualifications as a proposed authorized user for the types of use you have requested.

Response: Please see attached supplemental information including a letter signed by the Radiation Safety Officer from the University of California-Davis documenting the uses for which Dr. Narayan was authorized under their Agreement State broad scope license.

NRC Comment 2. Please be reminded that we cannot accept Dr. Narayan's specialty board certification, as of October 24, 2005.

Response: Dr. Narayan's board certification is acceptable for the purposes in our request in accordance with 10 CFR 35.57(b)(2). He was board certified in June 2003 and as documented in the attached information was approved for the uses in our current license. Accordingly, §35.57(b)(2) states, " Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by ... a permit issued by a Commission or Agreement State broad scope licensee... who

perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of this part."

NRC Comment 3. It appears that you may be trying to qualify Dr. Narayan under 10 CFR 35.57 or 35.13 and 35.14. If so, please state which regulation you are trying to qualify him under.

Response: Dr. Narayan's board certification is acceptable for the purposes in our request in accordance with 10 CFR 35.57(b)(2). He was board certified in June 2003 and as documented in our original submission and in the attached information from UC-Davis, he was approved for those uses in our current license.
In accordance with 10 CFR 35.14(a),"A licensee shall provide the Commission a copy ... the permit issued by a Commission or Agreement State licensee of broad scope, or ... no later than 30 days after the date that the licensee permits the individual to work as an authorized user, ...under §35.13(b)." We did supply a copy of the broad scope permit information from UC-Davis in our original submission. This was submitted prior to Dr. Narayan beginning duties at St. Joseph Mercy Hospital. The attached documentation supplements that submission. Accordingly, Dr. Narayan met the exception criteria of §35.13(b)(4)(ii) which required an amendment approval prior to working as an authorized user except for an AU on a permit issued by a Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use.

NRC Comment 4. It appears that you only want Dr. Narayan authorized for materials in 10 CFR 35.396, as opposed to "10 CFR 35.300 (excluding iodine-131." If so, please confirm and provide sufficient training and experience information, in accordance with 10 CFr 35.396 (or another section of 35.300) to support your request. Please note, your letter dated June 8.2007, did assert that Dr. Narayan was approved for any 10 CFR 35.300 authorization at UC-Davis.

Response: We agree with your clarification that we wished to request authorization under 10 CFR 35.396(b). Because of the written documentation needed to comply with §35.396(d) and not wishing to delay this licensing action further, we withdraw the request for this authorized use at this time and will pursue as a separate future amendment action.

NRC Comment 5. Please confirm that Dr. Narayan should only be authorized for the use of the HDR device on your license for "materials in 10 CFR 35.600," which excludes both GSR (gamma knife) and teletherapy, which are not authorized by this license. If it is appropriate to support Dr. Narayan's authorization request, please provide sufficient training and experience information to demonstrate compliance with 10 CFR 35.690.

Response: We agree with your clarification that we are requesting Dr. Narayan be authorized for use of the HDR machine under our license for materials in 10 CFR 35.600.

NRC Comment 6: As no materials under 10 CFR 35.1000 are authorized by this license, Dr. Narayan cannot be approved as an authorized user for materials under 35.1000 on this license, so we will disregard this request.

Response: We agree with your clarification. Our intent was to document all Dr. Narayan's training and experience with NRC authorized materials and uses. We apologize for the unintended confusion.

The information being submitted is complete and accurate taking all reasonable means and to best of our abilities.

cc: S. Narayan, MD

UNIVERSITY OF CALIFORNIA, DAVIS

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UC DAVIS MEDICAL CENTER
2315 STOCKTON BOULEVARD
SACRAMENTO, CALIFORNIA 95817

September 6, 2007

Dear Mr. Lieto,

This letter is to verify that Samir Narayan, M.D. was authorized to use radioactive material in the capacity of an attending radiation oncologist at the University of California Davis Medical Center from July 2003 to July 2007.

He had authorization under Radiation Use Authorization 9050 under our broad scope license 1334-57 to use radioactive materials for brachytherapy and our remote afterloader procedures, Groups 6 and 8. at UCDHS (Radioactive Material License #1334-57) and authorized under the following sections of 10 CFR 35:

35.400 Use of sources for manual brachytherapy
35.600 Use of sealed source in a remote afterloader unit. (We do not have any teletherapy units and he was not trained on the use of our gamma stereotactic radiosurgery unit.)
35.690 Authorized for remote afterloader use and maintained competency by completing annual emergency training for the remote afterloader.

See attached radiation use authorization with his name as an authorized user. Please exclude the attached pages from public document review.

Please call me at (916) 734-7325 if have any questions.

Sincerely,

Linda Kroger

Linda Kroger, MS
Radiation Safety Officer
UC Davis Health System

Attachment

S:\APS\EHS\Health\RUA_DOCS\9050\Narayan.wpd

UC Davis Health System — RUA No: 9050

Radiation Use Authorization — *27-Sep-06*

Amendment: 2006 - 6 **Type:** Human
Hazard Rating: 4 **Hazard Guide Value:** 28398490.00
PI: Srinivasan Vijayakumar **Alternate PI:** Janice Ryu
Department: Radiation Oncology **Lab Phone:** 4-8295
Renewal Month: September **Recharge No:** S429813

A. Authorized Radionuclides, Amounts, Forms

Isotope	Chem Form	Possession Limit (mCi)	Exper Limit (mCi)
Co-60	Sealed Sources-GammaKnife	6600000	6600000
Cs-137	Sealed Sources-Brachy	1000	
I-125	Sealed Sources-Brachy	1000	
Ir-192	Sealed Sources	21000	
Sr-90	Sealed Source	10	10
Sr-90	Sealed Source-Ophthalmic Appl	100	100

B. Authorized Radionuclides and Protocols

Isotope	Chem Form	Protocol No	Protocol Title
Co-60	Sealed Sources-GammaKnife	215	Loading of sources into Leksell Gamma Knife, acceptance testing, training, calibration, and physics testing in accordance with manfacturer's manuals and recomendations.
Cs-137	Sealed Sources-Brachy	27	Safety Protocol for Brachytherapy
I-125	Sealed Sources-Brachy	27	Safety Protocol for Brachytherapy
Ir-192	Sealed Sources	29	MicroSelectron-HDR Remote Afterloading System Requirements
Ir-192	Sealed Sources	27	Safety Protocol for Brachytherapy
Sr-90	Sealed Source	28	The 10 mCi Sr-90 source may be used for checking the constancy of thimble type ionization chamber's output.
Sr-90	Sealed Source-Ophthalmic Appl	27	Safety Protocol for Brachytherapy

C. Authorized Personnel

See Attached Listing

D. Authorized Locations

UC Davis Health System **RUA No: 9050**

Radiation Use Authorization 17 Sep 96

Confidential Information

E. Dosimetry Requirements

1. Personal dosimeters will be worn at all times when personnel are working with radioactive materials. (Not required when using the 10 mCi Sr-90 source)

2. A finger ring dosimeter shall be worn by personnel when they are handling sources, performing implants and/or preparing sealed sources for implants.

3. Dosimetry requirements in addition to the above as determined by the UCDMC Health Physics Office.

F. Bioassay Requirements

NONE

G. Survey Requirements

1. Radiation Oncology personnel who have received protocol-specific training or Health Physics staff shall perform appropriate radiological surveys during each implant.

2. Monthly monitoring by the Health Physics Office shall consist of an inspection of the records kept concerning the use of radioactive material under this RUA. In lieu of the monthly radiation survey by the UCDMC Health Physics Office, a quarterly inventory of the sealed sources shall be made by Health Physics personnel.

3. A dose rate meter (operational ion chamber survey meter, compensated GM) or GM survey meter shall be available during implant loading and removal and when radioactive materials are being used. While the implanted sources are in the patient, an instrument shall be on the unit where the patient's room is when the patient is on the ward. It is preferable to have an instrument in the patient's room. When the patient is transported to a different area of the Hospital and the implanted sources are still in the patient, a survey meter will be present at the patient's new location.

For I-125 radioactive implants, a thin window GM survey meter or NaI detector with meter shall be

present in the patient's hospital room at all times.

4. After the removal of an implanted sealed source(s), the Source Custodian, Alternate Source Custodian or a member of the UCDMC Health Physics staff shall perform appropriate surveys of the patient's room, linen and other areas as appropriate to confirm source removal. An immediate inventory of the sealed source(s) used shall be conducted and documented by the Source Custodian or Alternate Source Custodian before the patient leaves the hospital.

5. I-125 eye plaque patients who have the plaque sutured to their eye are allowed to leave the hospital and remain in their home for the treatment period. After the removal of low dose rate radioactive source implants, the patient shall remain in the hospital and may not be discharged until a source count and radiation survey of the patient confirm that all implants have been removed.

6. The Source Custodian or Alternate Source Custodian shall label the shipping container with the radioisotope, the number of seeds, and the total activity.

H. Instrument Calibration Requirements

1. The ion chamber survey meters and compensated GM meters shall be calibrated at least once each 12 months. GM survey meters shall be calibrated once per year. The Health Physics Office is responsible for the calibration of this equipment.

I. Authorized Use

1. Cancer and selected benign diseases shall be treated in accordance with established community standards.

2. Authorized users are listed on the personnel list for the RUA. The radioactive sources may be used for the planning and treatment of patients as prescribed by a physician certified by the American Board of Radiology or equivalent board certification in other countries if approved by the Radiologic Health Branch.

Radiation Oncology Physics staff, Radiology Physics staff and trained engineers may also operate the devices for calibrations, QA/QC testing and equipment repair.

All personnel who operate the HDR for patient use must have the appropriate therapeutic radiologic technology certification from the State of California. The certificate number and expiration dates of the qualified operators for patient treatments shall be posted.

3. Radioactive materials authorized by this RUA must be used in accordance with the safety protocols maintained in Section 1.C of the RUA Notebook and on file with the UCDHS Health Physics Office.

4. The 10 mCi Sr-90 source may be used for checking the constancy of thimble type ionization chambers' output.

5. Research involving non-standard therapies which may change radiation considerations or vary significantly from standard radiation treatment doses will be submitted to the Radiation Use Committee (RUC) on a Human Radiation Use Research Application. ~~If it is deemed non-standard (such as increasing therapy doses beyond the normal range) then the Radiation Oncology Department will obtain a written~~

Authorized Users	Training Expire Date	Category
Boggan, James	2/23/2007	LAB
Capostagno, Vincent	1/13/2007	LAB
Franklin, Stephen	1/9/2007	LAB
Goldberg, Zelanna	7/29/2008	LAB
Jacob, Rojymon	9/29/2007	LAB
Narayan, Samir	6/6/2009	LAB
Pappas, Conrad	1/22/2007	LAB
Ryu, Janice	12/27/2008	LAB
Sahrakar, Kamran	5/2/2008	LAB
Vijayakumar, Srinivasan	11/4/2008	LAB