

+ **PROVIDENCE**
Alaska
Medical Center

March 14, 2008

James Montgomery
Health Physicist
U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza, Suite 400
Arlington TX 76011

RECEIVED
MAR 17 2008
DNMS

Attention: Nuclear Materials Licensing Branch

RE: Amendment to Radioactive Materials License 50-17838-01
Addition of Dr Chakri S. Inampudi as an Authorized User for 35.1000 for
Yttrium-90 microspheres

Dear Mr. Montgomery,

We wish to amend our Radioactive Materials License to add Chakri S. Inampudi, M.D. as an Authorized User for 35.1000 for Yttrium-90 microspheres. Please note that Dr. Inampudi is an authorized user for 35.100 and 35.200 currently listed on our NRC Materials License. Please also note that Dr. Inampudi has implemented more than 20 Y-90 Sir-Spheres cases under the late AU Dr. Rodney Cook since June, 2005.

Please see the attached documents as follows:

1. NRC Form 313A (AUS), signed by Dr. Douglas Coldwell, AU and Preceptor.
2. A copy of Materials License 50-17838-01, with Dr. Douglas Coldwell as AU for 35.1000 for Yttrium-90 microspheres.
3. A copy of Board Certification of the American Board of Radiology of Dr. Inampudi.
4. A copy of Record of Training, signed by Neal McMahon, Regional Sales Manager of SirTex Medical.

If you have any questions, please do not hesitate to call Yongli Ning, Radiation Safety Officer at (907) 212-5691, or Christopher Galloway, Manager Cancer Therapy Center at (907) 212-6084.

Thank you for your assistance during this process.

Sincerely,

No. 4 7 1 7 2 5



A handwritten signature in black ink, appearing to read "Yongli Ning", written over a horizontal line.

Yongli Ning, M.S., Radiation Safety Officer and Chief Medical Physicist
Providence Alaska Medical Center

Cc:

Christopher Galloway, Clinical Manager Cancer Therapy Center
Wanda Katinszky, Director Oncology Service Line
Stephen Katzenson, Chairman Radiation Safety Committee
Bruce Lamoureux, Administrator Providence Alaska Medical Center

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

Chakri S. Inampudi, M.D.

Alaska

Requested

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)

Authorization(s)

35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)

(check all that apply)

35.600 Remote afterloader unit(s) 35.1000 Y-90 microspheres

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
- c. Skip to and complete Part II Preceptor Attestation.

2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above

- a. Go to the table in section 3.e. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

- a. Classroom and Laboratory Training 35.490 35.491 35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User
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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			

Supervising Individual. *If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)* License/Permit Number listing supervising individual as an Authorized User

Authorized for the following types of use:

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following for each requested authorization:

For 35.490:

Board Certification

I attest that Chakri S. Inampudi, M.D., M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User
35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User
classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User
classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User
35.690(a)(1).

OR

Training and Experience

I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User
and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

I attest that _____ has received training required in 35.690(c) for device
Name of Proposed Authorized User
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

I attest that _____ has achieved a level of competency sufficient to
Name of Proposed Authorized User
achieve a level of competency sufficient to function independently as an authorized user for:


- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

- 35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)
 35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)
 35.600 Remote afterloader unit(s) 35.1000 Y-90 microspheres

Name of Preceptor	Signature	Telephone Number	Date
Douglas M. Coldwell, M.D.		214.356.0443	3/5/08

License/Permit Number/Facility Name
NRC Materials License #50-17838-01, Amendment No. 47, Providence Alaska Medical Center

The American Board of Radiology

*Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine*

Hereby certifies that

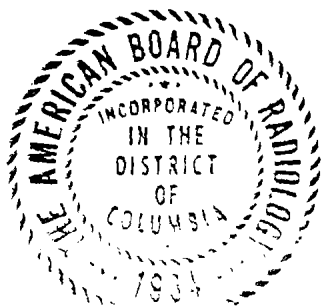
Chakri S. Inampudi, MB, BS

*Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology*

On this third day of June, 1998

*Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of*

Diagnostic Radiology



Irish S. Cavallaro MD
President

R.P. Hatten MD
Secretary-Treasurer

W. J. ... M.D.
Executive Director



Certificate No. 43764



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Suite 100
Lake Forest
IL 60045
Phone: (847) 482-9023
Fax: (847) 482-9103
Website: www.sirtex.com

RECORD OF TRAINING

The following people participated in Sirtex Medical training for the administration of Yttrium-90 microspheres (SIR-Spheres) at Providence Alaska Medical Center in Anchorage, Alaska

June 1, 2005 Advanced Training

Yongli Ning, M.S. Chief Medical Physicist
Michael Higgins, Nuclear Medicine Technician
Rodney Cook, M.D. Radiation Oncology, RSO
Chakri Inampudi, M.D. Interventional Radiologist

June 2, 2005 Two Clinical Treatments

Yongli Ning, M.S. Chief Medical Physicist
Michael Higgins, Nuclear Medicine Technician
Rodney Cook, M.D. Radiation Oncology, RSO
Chakri Inampudi, M.D. Interventional Radiologist

October 18, 2005 Two Clinical Treatments

Yongli Ning, M.S. Chief Medical Physicist
William Barnes, RTT, Radiological Engineer
Michael Higgins, Nuclear Medicine Technician
Rodney Cook, M.D. Radiation Oncology, RSO
Chakri Inampudi, M.D. Interventional Radiologist

Advance training was performed by Neal McMahon, Regional Sales Manager of Sirtex Medical and the clinical treatments were proctored by Randall Smith, M.D., Interventional Radiologist, Altru Hospital in Grand Forks, North Dakota.

By: _____

Handwritten signature of Neal McMahon in black ink.

Date: _____

Oct 19, 2005

Innovators in Oncology
