



Hospital of Saint Raphael

A member of the Saint Raphael Healthcare System

1450 Chapel Street • New Haven, Connecticut 06511 • 203.789.3000 • www.srhs.org

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REGION I

October 13, 2010

Licensing Assistance Section
Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03001238

License Amendment Request
License No. 06-00200-03

Gentlemen:

The Hospital of Saint Raphael in New Haven, Connecticut requests a license amendment granting authorized user status to Mehul K. Patel, M.D., for the following:

Material and Use: 35.600 Use of a Sealed Source of Iridium-192 in a High Dose Rate Remote Afterloader
35.400 Use of Manual Brachytherapy Sources

Dr. Patel joined the Medical Staff of the Hospital of Saint Raphael as an attending Radiation Oncologist in the Radiation Therapy Department in August of 2010. He is licensed to practice medicine in the State of Connecticut. Dr. Patel graduated from a four year Radiation Oncology Residency Program (ACGME Program #4302512046) offered by the Henry Ford Health System in Detroit, Michigan. Attached please find a completed NRC Form 313A (AUS), which documents Dr. Patel's qualifications for the requested uses.

The Hospital is also requesting that Suzanne B. Evans , MD, and Constantin Bogdan Marcu, M.D., be removed from the license effective October 15, 2010. Dr.Evans and Dr. Marcu are no longer members of the medical staff at the Hospital of Saint Raphael.

Please contact Charles Gignac, the Hospital Radiation Safety Officer, with any questions pertaining to this request. He can be contacted at 203-789-3292, or by e-mail at cgignac@srhs.org

Sincerely,

Christopher O'Connor
President and Chief Executive Officer
Hospital of Saint Raphael

573775
NMSS/RGN1 MATERIALS-002

NRC FORM 31A (AUS) (3-2009)		U.S. NUCLEAR REGULATORY COMMISSION																									
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: 3/31/2012																								
Name of Proposed Authorized User Mehul K. Patel MD		State or Territory Where Licensed Michigan, Florida																									
Requested Authorization(s) (check all that apply)	<input checked="" type="checkbox"/> 35.400 Manual brachytherapy sources	<input type="checkbox"/> 35.600 Teletherapy unit(s)	<input type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)																								
	<input checked="" type="checkbox"/> 35.400 Ophthalmic use of strontium-90	<input checked="" type="checkbox"/> 35.600 Remote afterloader unit(s)																									
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.																											
<input type="checkbox"/> 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. Sign to and complete Part II Preceptor Attestation.																											
<input type="checkbox"/> 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. Sign to and complete Part II Preceptor Attestation.																											
<input checked="" type="checkbox"/> 3. Training and Experience for Proposed Authorized User																											
a. Classroom and Laboratory Training <input checked="" type="checkbox"/> 35.490 <input type="checkbox"/> 35.491 <input checked="" type="checkbox"/> 35.690																											
<table border="1"> <thead> <tr> <th>Description of Training</th> <th>Location of Training</th> <th>Clock Hours</th> <th>Dates of Training*</th> </tr> </thead> <tbody> <tr> <td>Radiation physics and instrumentation</td> <td>Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202</td> <td>60 hours</td> <td>7/2006-6/2010</td> </tr> <tr> <td>Radiation protection</td> <td>Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202</td> <td>30 hours</td> <td>7/2006-6/2010</td> </tr> <tr> <td>Mathematics pertaining to the use and measurement of radioactivity</td> <td>Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202</td> <td>30 hours</td> <td>7/2006-6/2010</td> </tr> <tr> <td>Radiation biology</td> <td>Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202</td> <td>120 hours</td> <td>7/2006-6/2010</td> </tr> <tr> <td colspan="2" style="text-align: center;">Total Hours of Training:</td> <td colspan="2" style="text-align: center;">240</td> </tr> </tbody> </table>				Description of Training	Location of Training	Clock Hours	Dates of Training*	Radiation physics and instrumentation	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	60 hours	7/2006-6/2010	Radiation protection	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	30 hours	7/2006-6/2010	Mathematics pertaining to the use and measurement of radioactivity	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	30 hours	7/2006-6/2010	Radiation biology	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	120 hours	7/2006-6/2010	Total Hours of Training:		240	
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NRC FORM 313A (AUS)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Checking survey meters for proper operation	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Preparing, implanting, and safely removing brachytherapy sources	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Maintaining running inventories of material on hand	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Using administrative controls to prevent a medical event involving the use of byproduct material	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Using emergency procedures to control byproduct material	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010

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 checked="" 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	Henry Ford Health System Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	7/2006-6/2010
Supervising Individual Mohamed Elshalkh, MD	License/Permit Number listing supervising individual as an Authorized User Material License: 2104109-16	

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(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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	N/A		
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	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Preparing treatment plans and calculating treatment doses and times	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Using administrative controls to prevent a medical event involving the use of byproduct material	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Checking and using survey meters	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Blvd, Detroit,	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010
Selecting the proper dose and how it is to be administered	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Blvd, Detroit,	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006-6/2010

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U.S. NUCLEAR REGULATORY COMMISSION

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 checked="" 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	Henry Ford Health System 2104109-16 Department of Radiation Oncology 2799 W. Grand Boulevard, Detroit, MI 48202	7/2006-6/2010
Supervising Individual Mohamed Elshalkh, MD	License/Permit Number listing supervising individual as an Authorized User Material License: 2104109-16	

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	Provider: Physicists 7/2006-6/2010		
Safety procedures for the device use	Provider: Physicists 7/2006-6/2010		
Clinical use of the device	Providers: Authorized Users 7/2006-6/2010		

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.) Mohamed Elshalkh, MD	License/Permit Number listing supervising individual as an Authorized User 2194109-16
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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.

NRC FORM 31-A (AUS)
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.490:

Board Certification

I attest that _____ 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 **Mehul Patel, M.D.** 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 **Mehul Patel, M.D.** 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

NRC FORM 31:IA (AUS)
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690; (continued)

I attest that Mehul Patel, M.D. 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 Mehul Patel, M.D. 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

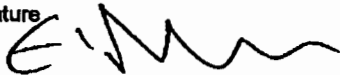
Complete the following for preceptor attestation and signature:

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

Name of Preceptor	Signature	Telephone Number	Date
Mohamed Elshaikh, M.D.		(313) 916-3689	09/14/2010

License/Permit Number/Facility Name
Material License 2104109-16