

NRC FORM 313

(4-2008)

10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIALS LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐

A. NEW LICENSE

☒B. AMENDMENT TO LICENSE NUMBER 21-02802-03☐

C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Providence Hospital
Department of Nuclear Radiology
16001 West Nine Mile Road
Southfield, MI 48037

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Providence Hospital
47601 Grand River, Novi, MI 48374
&
16001 West Nine Mile Rd, Southfield, MI 48037

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Vrinda Narayana, Ph.D.

TELEPHONE NUMBER

(248) 849-8622

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

AMOUNT
ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

Vrinda Narayana/ Chief Physicist

SIGNATURE



DATE

05/05/2011

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

RECEIVED MAY 06 2011



PROVIDENCE Cancer Institute

May 5 2011

U.S. Nuclear Regulatory Commission, Region III
Nuclear Materials Licensing
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Ref: Material License # # 21-02802-03,

Subject: Request for license material amendment

To the person concerned,

Enclosed is our request to amend our material license # **21-02802-03**, issued to Providence Hospital, 16001 West Nine Mile Road, Southfield, MI 48037..

Dr. Eyad Abu-Isa, MD will be joining our staff at Providence Hospital on August 1, 2011. I request that he be **added** as an Authorized User on our license for the use of material listed in 10 CFR 35.400 for manual brachytherapy. I have attached a preceptor signed NRC Form 313A(AUS) that documents his training and experience in anticipation of successfully completed his training at the University of Michigan.

Thank you,

Sincerely,

A handwritten signature in black ink, appearing to read "Vrinda Narayana".

Vrinda Narayana, Ph.D
Chief Physicist
22301 Foster Winter Drive, I Floor
Southfield, MI 48075
248 849 8622

cc: Allan D. Fraiberg, MD, RSO

**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

Eyad Abu-Isa, M.D.

State or Territory Where Licensed

Michigan

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)**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**

- Provide a copy of the board certification.
- 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.
- Skip to and complete Part II Preceptor Attestation.

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

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

☒ **3. Training and Experience for Proposed Authorized User**

- 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	University of Michigan, Radiotherapy Physics	174	09/07-04/08, 09/09-04/10
Radiation protection	University of Michigan, Annual Radiation Safety Refreshers and Radiotherapy Physics	7 (+ 3 hr from course)	07/07-05/11
Mathematics pertaining to the use and measurement of radioactivity	University of Michigan, Radiotherapy Physics	174	09/07-04/08, 09/09-04/10
Radiation biology	University of Michigan, Radiobiology	68	09/07-04/08, 09/09-04/10
Total Hours of Training:		249	

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: 9600 (in 4 year residency)	
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	University of Michigan, License # 21-00215-04 Providence Hospital and Medical Centers, License # 21-02802-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Checking survey meters for proper operation	University of Michigan, License # 21-00215-04 Providence Hospital and Medical Centers, License # 21-02802-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Preparing, implanting, and safely removing brachytherapy sources	University of Michigan, License # 21-00215-04 Providence Hospital and Medical Centers, License # 21-02802-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Maintaining running inventories of material on hand	University of Michigan, License # 21-00215-04 Providence Hospital and Medical Centers, License # 21-02802-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Using administrative controls to prevent a medical event involving the use of byproduct material	University of Michigan, License # 21-00215-04 Providence Hospital and Medical Centers, License # 21-02802-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Using emergency procedures to control byproduct material	University of Michigan, License # 21-00215-04 Providence Hospital and Medical Centers, License # 21-02802-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11

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	University of Michigan, License # 21-00215-04	07/2007 - 06/2011
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User # 21-00215-04	

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

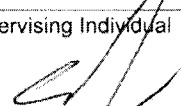
☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

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	University of Michigan, License # 21-00215-04	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Preparing treatment plans and calculating treatment doses and times	University of Michigan, License # 21-00215-04	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Using administrative controls to prevent a medical event involving the use of byproduct material	University of Michigan, License # 21-00215-04	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	University of Michigan, License # 21-00215-04	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Checking and using survey meters	University of Michigan, License # 21-00215-04	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11
Selecting the proper dose and how it is to be administered	University of Michigan, License # 21-00215-04	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/07-06/11

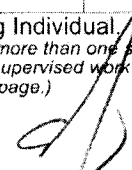
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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	University of Michigan, License # 21-00215-04	07/2007 - 06/2011
Supervising Individual 		License/Permit Number listing supervising individual as an Authorized User # 21-00215-04

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	1/08, 2/08, 2/09, 2/11 (annual refresher), 12/07, 1/08, 12/09, 1/10 (radiotherapy course)	N/A	N/A
Safety procedures for the device use	1/08, 2/08, 2/09, 2/11 (annual refresher), 12/07, 1/08, 12/09, 1/10 (radiotherapy course)	N/A	N/A
Clinical use of the device	1/08, 2/08, 2/09, 2/11 (annual refresher), 12/07, 1/08, 12/09, 1/10 (radiotherapy course)	N/A	N/A
Supervising Individual <i>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.)</i> 		License/Permit Number listing supervising individual as an Authorized User # 21-00215-04	
Authorized for the following types of use: <input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> 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.

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 Eyad Abu-Isa 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 Eyad Abu-Isa 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 Eyad Abu-Isa 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 Eyad Abu-Isa 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

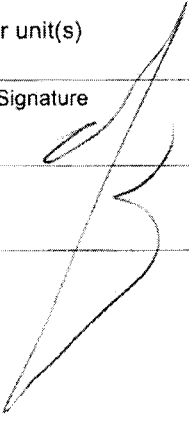
Complete the following for preceptor attestation and signature:

☒ 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)

Name of Preceptor Edgar Ben-Josef, M.D.	Signature 	Telephone Number (734) 936-8207	Date 5-3-11
License/Permit Number/Facility Name University of Michigan, License # 21-00215-04			

UPS CampusShip: View/Print Label

1. **Print the label(s):** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.
2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. GETTING YOUR SHIPMENT TO UPS**Customers without a Daily Pickup**

Schedule a same day or future day Pickup to have a UPS driver pickup all your CampusShip packages.

Hand the package to any UPS driver in your area.

Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return ServicesSM (including via Ground) are also accepted at Drop Boxes.

To find the location nearest you, please visit the Resources area of CampusShip and select UPS Locations.

Customers with a Daily Pickup

Your driver will pickup your shipment(s) as usual.

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VRINDA NARAYANA 248.849.8622 PROVIDENCE CANCER CENTER - SOU 22301 FOSTER WINTER DR. SOUTHFIELD MI 48075		0.1 LBS LTR	1 OF 1
SHIP TO: MATERIALS LICENSING BRANCH US NRC REGION III SUITE 210 2443 WARRENVILLE ROAD LISLE IL 60532-4352			
	IL 603 9-03 		
UPS NEXT DAY AIR SAVER 1P TRACKING #: 1Z W22 100 13 9292 8801 			
BILLING: P/P			
LHM: SOUCAN Cost Center: 807152		CS 13.1.13. WXP1E70 15.0A 04/2011	