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October 24, 2013

US NUCLEAR REGULATORY COMMISSION
Division of Nuclear Materials Safety
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Licensee: Centro de Radioterapia Auxilio Mutuo
License Number 52-30937-01 *103036635*

Subject: Resubmit of Additional Authorized User request for License #52-30937-01

To whom it may concern:

It is hereby requested that Javier Lopez MD be designated as an Authorized User for 35.600 Remote Afterloader unit on our byproduct material license #52-30937-01.

Supporting documentation is attached.

Thank you for your prompt attention to this matter.

Enid Dohnert, Associate Administrator
Centro de Radioterapia Auxilio Mutuo

590640
NMSS/RGNI MATERIALS-002

NRC FORM 313 (04-2010) 10 CFR 30.32, 33, 34 35.30, 37, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION <div style="text-align: center;"> APPLICATION FOR MATERIALS LICENSE </div>	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 04/30/2016 Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submit 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 FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to InfoCollection.Resource@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (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.																		
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. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.																				
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NRC FORM 313A (AUS)
(04-2016)

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. 3160-0120
EXPIRES: 04/30/2018

Name of Proposed Authorized User

Javier J. López Araujo

State or Territory Where Licensed

Puerto Rico

Requested

Authorization(s)

(check all that apply)

- ☒ 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)

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	University of Alabama at Birmingham Department of Radiation Oncology	116	7/1/11-6/30/15
Radiation protection	University of Alabama at Birmingham Department of Radiation Oncology	53	7/1/11-6/30/15
Mathematics pertaining to the use and measurement of radioactivity	University of Alabama at Birmingham Department of Radiation Oncology	36	7/1/11-6/30/15
Radiation biology	University of Alabama at Birmingham Department of Radiation Oncology	1363	7/1/11-6/30/15

Total Hours of Training: 1568

NRC FORM 313A (AUS) (04-2015)	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. 3160-0120 EXPIRES: 04/30/2018																					
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NRC FORM 313A (AUS)
(04-2018)

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	Yes	Total Hours of Experience:	1096
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 Alabama at Birmingham Department of Radiation Oncology 11 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Checking survey meters for proper operation	University of Alabama at Birmingham Department of Radiation Oncology 6 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Preparing, implanting, and safely removing brachytherapy sources	University of Alabama at Birmingham Department of Radiation Oncology 1065 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Maintaining running inventories of material on hand	University of Alabama at Birmingham Department of Radiation Oncology--5 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Using administrative controls to prevent a medical event involving the use of byproduct material	University of Alabama at Birmingham Department of Radiation Oncology 4 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Using emergency procedures to control byproduct material	University of Alabama at Birmingham Department of Radiation Oncology 5 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15

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 Alabama at Birmingham Department of Radiation Oncology	7/1/11-6/30/15
Supervising Individual Omer Lee Burnett III, M.D., Program Director		License/Permit Number listing supervising individual as an Authorized User PA-105 and 314 (J. A. Bonner/I. Brezovich)

NRC FORM 313A (AUS)
(04-2016)

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			
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:	
yes		1752	
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 Alabama at Birmingham Department of Radiation Oncology 17 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Preparing treatment plans and calculating treatment doses and times	University of Alabama at Birmingham Department of Radiation Oncology 1522 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Using administrative controls to prevent a medical event involving the use of byproduct material	University of Alabama at Birmingham Department of Radiation Oncology 6 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	University of Alabama at Birmingham Department of Radiation Oncology 11 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Checking and using survey meters	University of Alabama at Birmingham Department of Radiation Oncology 12 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15
Selecting the proper dose and how it is to be administered	University of Alabama at Birmingham Department of Radiation Oncology 184 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/11-6/30/15

NRC FORM 313A (AUS)
(04-2016)

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	University of Alabama at Birmingham Department of Radiation Oncology	7/1/11-6/30/15
Supervising Individual Omer Lee Burnett III, MD, Program Director		License/Permit Number listing supervising individual as an Authorized User PA-105 and 314 (J.A. Bonner and I. Brezovich)

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	R. Kim, O. Burnett, I. Brezovich, S. Shen, R. Popple 7/1/11-6/30/15	J. Bonner, S. Spencer, J. Fiveash, R. Kim, O. Burnett, S. Yang, C. Willey, et al. 7/1/11-6/30/15	
Safety procedures for the device use	R. Kim, O. Burnett, I. Brezovich, S. Shen, R. Popple 7/1/11-6/30/15	J. Bonner, S. Spencer, J. Fiveash, R. Kim, O. Burnett, S. Yang, C. Willey, et al. 7/1/11-6/30/15	
Clinical use of the device	R. Kim, O. Burnett, I. Brezovich, S. Shen, R. Popple 7/1/11-6/30/15	J. Bonner, S. Spencer, J. Fiveash, R. Kim, O. Burnett, S. Yang, C. Willey, et al. 7/1/11-6/30/15	
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.) Omer Lee Burnett III, M.D., Program Director		License/Permit Number listing supervising individual as an Authorized User PA-105 and 314 (J.A. Bonner and I. Brezovich)	
Authorized for the following types of use: <input checked="" type="checkbox"/> Remote afterloader unit(s) <input checked="" type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

NRC FORM 313A (AUS)
(04-2016)

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 _____ 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 Javier J. López Araujo 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 313A (AUS)
(04-2016)

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 Javier J. López Araujo 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 Javier J. López Araujo 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)

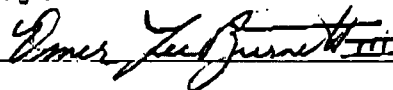
Name of Preceptor

Signature

Telephone Number

Date

Omer Lee Burnett III, M.D.



(205) 837-8554

7 April 2016

License/Permit Number/Facility Name

University of Alabama at Birmingham, Department of Radiation Oncology, PA-105 and 314 (J.A. Bonner and I. Brezovich)

NRC FORM 313A (AUS)
(04-2016)

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 Javier J. López Araujo 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 Javier J. López Araujo 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

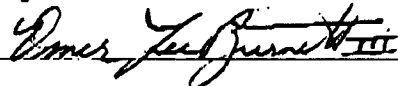
Complete the following for preceptor attestation and signature:

☒ 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	Signature	Telephone Number	Date
Omer Lee Burnett III, M.D.		(205) 837-8554	7 April 2016

License/Permit Number/Facility Name

University of Alabama at Birmingham, Department of Radiation Oncology, PA-105 and 314 (J.A. Bonner and I. Brezovich)

This is to acknowledge the receipt of your letter/application dated

04/08/2016, and to inform you that the initial processing which includes an administrative review has been performed.

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 590640.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader.