Guam Medical Imaging Center

Suite 111 PeMar Place
472 Chalan San Antonio
Tamuning Guam 96913
Phone: (671) 649-9227 / Fax: (671) 649-9228

April 10, 2015

To: Nuclear Materials Licensing/Amendments Section
U.S. Nuclear Regulatory Commission, Region IV
1600 E. Lamar Blvd
Arlington, Tx. 76011-4511

Subj: Amendment of Materials Permit (56-27702-01)

1. Please add and amend the following individual as an Authorized Users to our materials license:

License number: 56-27702-01

A. Mallikarjunappa, M.D. - meets qualifications outlined in
10CFR 35.300, - 35.390, 35.392, 35.394, 35.396
Please list as an Authorized User
1. Completed NRC Form 313A (AUT) University of Washington (Encl 1)
2. Board Certification, American Board of Nuclear Medicine (Encl 2)
3. Board Certification, American Board of Radiology (Encl 3)

B. Please remove the following Authorized Users from Permit 56-27702-01
1. Andrew C. Breiterman, MD
2. James A. Moeller, DO

- Both physicians no longer practice medicine on the island of Guam.

2. Please contact Stephen Amos, manager, at (671) 688-9252 with any questions concerning this amendment. Guam is 15 hours ahead of the Midwest time zone.

Thank you,

Nathaniel B. Berg, M.D.
Radiation Safety Officer
Guam Medical Imaging Center

NRC FORM 313A (AUT) (05-2012) | U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
Malli-Karjunappa	Guam

Requested Authorization(s) *(check all that apply)*:

- [x] 35.300 Use of unsealed byproduct material for which a written directive is required

OR

- [ ] 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- [ ] 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)
- [ ] 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- [ ] 35.300 Parenteral administration of any other radionuclide for which a written directive is required

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 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.

- [x] **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

- [ ] **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

[ ] 35.390 [ ] 35.392 [ ] 35.394 [ ] 35.490 [ ] 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

No 586582

NRC FORM 313A (AUT)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.390 ☑ 35.392 ☑ 35.394 ☑ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
David H Lewis, MD	David H Lewis, MD	2067443471	9/25/2014

License/Permit Number/Facility Name
WN-C001-1 University of Washington

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

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			
Chemistry of byproduct material for medical use			
Radiation biology			
	Total Hours of Training: ☐		

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, 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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

With experience administering dosages of:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	10	WN-C001-1	7/1/2011 10/21/2012
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	8	"	"
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	2	"	"
Parenteral administration of any other radionuclide for which a written directive is required Y-90 (List radionuclides)	20	"	"

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
David H Lewis, MD	WN-C001-1

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

- ☑ 35.390
- ☑ 35.392
- ☑ 35.394
- ☑ 35.396

With experience administering dosages of:

- ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☑ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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 35.390:

Board Certification

☑ I attest that Mallikarjunappa, MD has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

☐ I attest that _____ has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that _____ has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

The American Board of Nuclear Medicine

Incorporated 1971

Certifies that

Mallikarjunappa MK, M.D.

has met the requirements of this Board and is qualified during the period of 2012 through 2022 to practice as a Specialist in all aspects of Clinical and Laboratory

Nuclear Medicine

Maintenance of this certificate requires full participation in the ABNM's Maintenance of Certification program.

Kirk A. Frey, M.D., Ph.D.
Chairman

08534
Number

United States

Louis P. O'Malley, M.D.
Secretary-Treasurer

ABMS MOC™
American Board of Nuclear Medicine
Certification Matters

M 5 8 6 5 8 2

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 Radiation Oncology, the Association of
University Radiologists, and the American Association of Physicists in Medicine,
Hereby certifies that

Mallikarjunappa

Has pursued an accepted course of graduate study and clinical work; has met certain standards and qualifications, including passing the examinations conducted under the authority of the American Board of Radiology, demonstrating to the satisfaction of the Board qualification to practice; and is therefore awarded the Board's certification in

Diagnostic Radiology

AU Eligible

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

Ongoing validity of this certificate is contingent upon meeting the requirements of Maintenance of Certification.

This diplomate of the American Board of Radiology is permitted to use the **DABR** *mark to signify this certification.*

President

Richard T. Morin
Secretary-Treasurer

Executive Director

DABR

AMERICAN BOARD OF MEDICAL SPECIALTIES
1933
EXCELLENCE

Certificate No. 65220

Effective: August 31, 2012

FedEx Express

International Air Waybill

8077 0488 9214

FedEx Tracking Number

Form ID No. 040

1 From

Date

Sender's FedEx Account Number

Sender's Name

Phone

Company

Address

Address

City

State Province

Country

ZIP Postal Code

2 To

Recipient's Name

Phone

Company U.S. NUCLEAR REGULATORY

Address

Address 1600 E. LAMAR BLVD

Dept/Floor

City ARLINGTON

State Province TX

Country

ZIP Postal Code 76011

Recipient's Tax ID Number for Customs Purposes
e.g., GST/RFC/VAT/IN/EIN/ABN, or as locally required.

3 Shipment Information

☐ For EU Only: Tick here if goods are not in free circulation and provide C.I.

Total Packages (Shipper's Load and Count/SLAC)

Total Weight ☐ lbs. ☐ kg

DIM / / ☐ in. ☐ cm

Commodity Description	Harmonized Code	Country of Manufacture	Value for Customs
FOS			NCV

Has EEI been filed in AES? *For U.S. Export Only: Check One*

☐ No EEI required, value $2,500 or less per Sch. B Number, no license required (NLR), not subject to ITAR.

☐ No EEI required, enter exemption number:

If other than NLR, enter License Exception:

☐ Yes – Enter AES proof of filing citation:

Total Declared Value for Carriage

Total Value for Customs (Specify Currency)

4 Express Package Service

Packages up to 150 lbs. / 68. For packages over 150 lbs. (68 kg), use FedEx Expended Service Intl. Air Way

1 ☐ FedEx Intl. Priority

6 ☐ FedEx Intl. First — Available to select locations.

☐ ☐ ☐

3 ☐ FedEx Intl. Economy — FedEx Envelope and FedEx Pak rate not available.

5 Packaging

*These unique brown boxes with special pricing provided by FedEx for FedEx Intl. Priority

6 ☐ FedEx Envelope 2 ☐ FedEx Pak 3 ☐ FedEx Box 4 ☐ FedEx Ti

1 ☐ Other PW ☐ FedEx 10kg Box* PX ☐ FedEx 25kg B

6 Special Handling

1 ☐ HOLD at FedEx Location 3 ☐ SATURDAY Delivery — Available to select locations for FedEx Intl. Priority only.

7 Payment

Complete payment options for transportation charges and duties and t

Bill transportation charges to:

Enter FedEx Acct. No. or Credit Card No. below.

1 ☐ Sender Acct. No. in Section 1 will be billed. 2 ☐ Recipient 3 ☐ Third Party 4 ☒ Credit Card 5 ☐ Cash Check/Che

Total Transporte

FedEx Acct. No.

Credit Card Exp. Date

Specify Curre

Bill duties and taxes to:

ALL shipments may be subject to Customs cha which FedEx does not estimate prior to clear

Enter FedEx Acct. No. below.

1 ☐ Sender Acct. No. in Section 1 will be billed. 2 ☐ Recipient 3 ☐ Third Party 5 ☐ Cash Check/Cheque

FedEx Acct. No.

8 Your Internal Billing Reference

First 24 characters will appear on in

9 Required Signature

Use of this Air Waybill constitutes your agreement to the Conditions of Contract on the back of this A Waybill, and you represent that this shipment does not require a U.S. State Department License or c dangerous goods. Certain international treaties, including the Warsaw Convention, may apply to thi shipment and limit our liability for damage, loss, or delay, as described in the Conditions of Contract. WARNING: These commodities, technology, or software were exported from the United States in accor with Export Administration Regulations. Diversion contrary to U.S. law prohibited.

Sender's Signature:

This is not authorization to deliver this shipment without a recipient signature.

Received above shipment in good order and condition. We agree to pay all charges, including Customs dutie taxes as applicable, and we agree to the Conditions of Carriage as stated on the reverse side of the Recipient

Recipient's Signature:

FedEx Tracking Number 8077 0488 9214 04

Origin Station ID	Country Code/Destination Station ID	URSA Routing
DFW	NCHH	

Received At: 1 ☐ Reg. Stop 2 ☐ On-Call Stop 3 ☐ Drop Box 4 ☐ World Service Center 5 ☐ Station

Basic Charges | Declared Val. Chrg. | Other | ODA/ IOPA | C

FedEx Emp. # | Audit Emp. # | Date | Time | Del. Courier Emp. #

Non-Negot

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OA
INTL PRIORITY CLR
CLR
76011
TX-US
DFW

7 0488 9214

FWHA

IND 04/17 513G2/8FC5/AA44

Stephen Arnos
Federal Express
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4/17/2015
1122

HILL, Carol

RECEIVED
APR 17 2015
DNMS

RTE:
MSC:

5 8 6 5 8 2

1

NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

04/21/2015

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Stephen Amos Clinic Manager/Imaging Director Guam Medical Imaging Center 472 Chalan San Antonio, Suite 111 Tamuning, Guam 96913	56-27702-01
	MAIL CONTROL NUMBER 586582
	LICENSING AND/OR TECHNICAL REVIEWER CH

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 04/10/2015

The initial processing, which included an administrative review, has been performed.

☑ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

☐ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER.** When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

NRC FORM 532
(1-2012)

✓ 4/21

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02120
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 05/31/2011
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	Guam Medical Imaging Center
Received Date:	04/17/2015
Docket Number:	3035716
Mail Control Number:	586582
License Number:	56-27702-01
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L Heeie

Date: 4/21/15

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

_____

Signed: _____

Date: _____