RALEIGH GENERAL HOSPITAL

*We touch lives*

NMSB2

Date: January 2, 2007

RECEIVED
REGION 1
2007 JAN -5 PM 12: 50

US Nuclear Regulatory Commission, Region II
475 Allendale Road
King of Prussia, PA 19406-1415

03014390

Gentlemen:

Re: Amendment to Radioactive Material License No. 47-18046-01

We request an amendment to the above material license to have part 35.300 added for Dr Mercedes Ramas.

Included with this letter is a copy of a letter from her preceptor that acknowledges her required training and Board Certification in Diagnostic Radiology by the American Board of Radiology. Also included is a preceptor statement from Raleigh General Hospital where she has worked since July 2003.

Thank you for your attention to this request. If supplemental information is required, please contact Larry Johnston CNMT, RT(N), at 304-256-4126, Larry.Johnston@LPNT.net, or Fax 304-256-4038.

Sincerely,

Karen L. Bowling
President/ Chief Executive Officer

139923

NUCLEAR MATERIALS-038

1710 Harper Road • Beckley, West Virginia 25801 • Telephone (304) 256-4100 • Fax (304) 256-4009
www.raleighgeneral.com

RALEIGH GENERAL HOSPITAL

*We touch lives*

# PRECEPTOR STATEMENT

DATE: December 28, 2006

To: US Nuclear Regulatory Commission, Region II

Re: Mercedes Ramas MD

Gentleman:

We the undersigned have observed Dr. Mercedes Ramas while she has Observed and administered I-131 for hyperthyroid therapy. She observed 4 cases and administered 9 cases with supervision between September 2005 Until November 2006, at Raleigh General Hospital.

Sincerely,

C.Richard Daniel jr., MD

Shawn Reesman, MD

Alan Lintala, MD

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NRC FORM 313A (AUT) (10-2006) 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: 10/31/2008

| Name of Proposed Authorized User | State or Territory Where Licensed |
|---|---|
| Mercedes Ramas MD | West Virginia |

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.

## 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 |
|---|---|

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.

**First Section**
**Check one of the following for each requested authorization:**

See Inclosed letters

**For 35.390:**

**Board Certification**

☐ I attest that _____ 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

NRC FORM 313A (AUT)
(10-2006)

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 adminstration 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 adminstration 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 |
|---|---|---|---|
| See Enclosed Letters | | 304-256-4100 | 12/28/06 |

License/Permit Number/Facility Name
47-18046-01 Raleigh General Hospital

# The American Board of Radiology

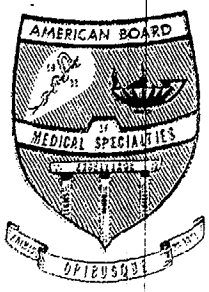
*Organized through the cooperation of the*
*American College of Radiology, the American Roentgen Ray Society,*
*the American Radium Society, the Radiological Society of North America,*
*the Section on Radiology of the American Medical Association,*
*the American Society for Therapeutic Radiology and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

## Mercedes E. Ramas, MD

*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 seventeenth day of May, 2000*
*Thereby demonstrating to the satisfaction of the Board*
*that she is qualified to practice the specialty of*

## Diagnostic Radiology




R.P. Hartery M.D.
President

Steven A. Seibel, M.D.
Secretary-Treasurer

M. [illegible], M.D.
Executive Director

Certificate No. 44389

MCV Campus

Virginia Commonwealth University

Health System
MCV Hospitals and Physicians

Department of Radiology
Division of Nuclear Medicine

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804 827-4984

Jerry I. Hirsch, Pharm.D.
804 828-8267

Joseph D. Kalen, Ph.D., MSHA
804 828-1443

Sharon R. Gibbs, BS, CNMT
Manager
804 828-4175

## PRECEPTOR STATEMENT

**Date: February 11, 2004**

**To: Raleigh General Hospital**

**RE: Mercedes Ramas, MD**

**Dr. Mercedes Ramas satisfies the requirements for imaging and localization studies (10 CFR 35.920) by successful completion of the Diagnostic Radiology Residency Training Program at Virginia Commonwealth University's Medical College of Virginia Hospitals from July 1, 1997 through June 30, 2000 and by receiving Board Certification in Diagnostic Radiology by the American Board of Radiology.**

**During her residency training, Dr. Ramas received the required training in the following areas:**

**200 hours of classroom and laboratory training**
**500 hours of supervised work experience**
**500 hours of supervised clinical experience**

**Experience in radiopharmaceutical preparation and in the use of therapeutic radiopharmaceuticals is documented on the following pages.**

**Sincerely,**

**Paul R. Jolles, MD**
**Associate Professor of Radiology**
**Program Director, Nuclear Medicine**

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT — U.S. NUCLEAR REGULATORY COMMISSION

## TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED |
|---|---|
| Mercedes Ramas | WV |

**3. CERTIFICATION**

| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C |
|---|---|---|
| American Board of Radiology | | 05/00 |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY | TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | MCV See letter | | |
| b. RADIATION PROTECTION | MCV See letter | | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | MCV See letter | | |
| d. RADIATION BIOLOGY | MCV See letter | | |
| e. RADIOPHARMACEUTICAL CHEMISTRY | MCV see letter | | |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | mCi USED AT ONE TIME | LOCATION | CLOCK HOURS | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — U. S. NUCLEAR REGULATORY COMMISSION

## PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP CODE

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1-Supervised examination of patient to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D |
|---|---|---|---|
| | Thyroid scan | | |
| | Thyroid uptake | | |
| | Lung perfusion scan | | |
| | Xenon ventilation study | | |
| | Aerosol ventilation scan | | |
| | Renal flow scan | | |
| | Brain scan | | |
| | Liver/spleen scan | | |
| | Bone scan | | See letter |
| | Gastroesophageal study | | |
| | LeVeen shunt study | | |
| | Cystogram | | |
| | Dacryocystogram | | |
| | Cardiac perfusion scan. | | |
| | Cardiac stress ventriculogram | | |
| | Cardiac rest ventriculogram | | |
| | Gallium scan | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

**PRECEPTOR STATEMENT** *(Continued)*

**2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN** *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | 4 | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | 10 | |
| Other | | | |

**3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING**

| LOCATION | DATES | CLOCK HOURS OF EXPERIENCE |
|---|---|---|
| | | See letter |

**4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:**

a. NAME OF SUPERVISOR: Lakshmana Das Narla, M.D.

b. NAME OF INSTITUTION: P.O. Box 980615

c. MAILING ADDRESS: Richmond, VA 23298-0615

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE: Paul N Jolles

7. PRECEPTOR'S NAME *(Please type or print)*: PAUL N. JOLLES, MD

8. DATE: 2/13/04

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

1/21/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☑ Amend. 47-18046-01
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** 139923.
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