



*We touch lives*

Date: January 26, 2007

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

*MS 16  
K-8*

Gentlemen:

*03014390*

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. For Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

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.nci](mailto:Larry.Johnston@LPNT.nci), or Fax 304-256-4038.

Sincerely,

*Karen L. Bowling*  
Karen L. Bowling  
President/ Chief Executive Officer

*139923*

NMCS/PGNI MATERIALS-002

NRC FORM 313A (AUT) <small>(10-2006)</small>	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
<b>AUTHORIZED USER TRAINING AND EXPERIENCE          AND PRECEPTOR ATTESTATION</b> (for uses defined under 35.300) <b>[10 CFR 35.390, 35.392, 35.394, and 35.396]</b>		

Name of Proposed Authorized User <i>Mercedes Ramas MD</i>	State or Territory Where Licensed <i>West Virginia</i>
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Requested Authorization(s) (check all that apply):

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.

**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.

NRC FORM 313A (AUT)  
(10-2005)

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 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 With experience administering dosages of:
- 35.392  Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- 35.394  Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- 35.396  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:

For 35.390:

Board Certification

I attest that Mercedes Ramos M.D. has satisfactorily completed the training and experience requirements in 35.390(a)(1).  
Name of Proposed Authorized User

**OR**

Training and Experience

I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).  
Name of Proposed Authorized User

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

U.S. NUCLEAR REGULATORY COMMISSION

**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 Mercedes Ramas M.D. 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 Mercedes Ramas M.D. 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 Mercedes Ramas M.D. 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 Mercedes Ramas M.D. 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 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

*C. R. DANIEL, JR, M.D.*

Signature

*[Handwritten Signature]*

Telephone Number

*304 256 4100*

Date

*1-30-07*

License/Permit Number/Facility Name

*47-18046-01*

*Raleigh General Hospital*