

BARBARA ANN
KARMANOS
CANCER CENTER
At the Detroit Medical Center

June 3, 2016

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

Attn: Sara Forster

Re: Additional Information Request for Authorized User Status for License #21-04127-06

Dear Ms. Forster,

Please find attached the additional information requested in your 6/1/2016 email concerning the authorized user amendment request for Drs. Dominello and Paximadis.

If you require further information please feel free to contact me at (313) 576-9616 or Rakowski@karmanos.org. Thank you.

Sincerely,



Joe Rakowski
Radiation Safety Officer
Karmanos Cancer Center
4100 John R St., Mail Code GE00RO
Detroit, MI 48201

Enclosure: NRC Forms 313A (AUT)

4100 John R
Detroit, Michigan 48201
(800) KARMANOS (1-800-527-6266)
info@karmanos.org | www.karmanos.org



**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

Michael Dominello, D.O.

MI

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 21-04127-06 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

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	Wayne State University/Karmanos Cancer Center Medical Residency	40	6/1/2011 to 6/30/2015
Radiation protection	Wayne State University/Karmanos Cancer Center Medical Residency	40	6/1/2011 to 6/30/2015
Mathematics pertaining to the use and measurement of radioactivity	Wayne State University/Karmanos Cancer Center Medical Residency	40	6/1/2011 to 6/30/2015
Chemistry of byproduct material for medical use	Wayne State University/Karmanos Cancer Center Medical Residency	40	6/1/2011 to 6/30/2015
Radiation biology	Wayne State University/Karmanos Cancer Center Medical Residency	40	6/1/2011 to 6/30/2015
Total Hours of Training:		<input type="text" value="200"/>	

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: 35	
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	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11/15/15 to 3/31/16
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11/15/15 to 3/31/16
Calculating, measuring, and safely preparing patient or human research subject dosages	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11/15/15 to 3/31/16
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11/15/15 to 3/31/16
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11/15/15 to 3/31/16

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
Nitin Vaishampayan, M.D.	21-04127-06

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.

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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
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	2/17/16: 136.6 uCi 2/24/16: 133.4uCi 3/28/16: 196.4uCi	Karmanos Cancer Center/21-04127-06	2/1/16 to 4/1/16
Parenteral administration of any other radionuclide for which a written directive is required <div style="border: 1px solid black; height: 30px; width: 100%;"></div> (List radionuclides)			

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 Michael Dominello, D.O. 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 Nitin Vaishampayan, M.D.	Signature 	Telephone Number (313) 503-2456	Date 6/3/16
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License/Permit Number/Facility Name
Karmanos Cancer Center/21-04127-06

**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

Peter Paximadis, M.D.

MI

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 21-04127-06 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

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	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2009 to 6/30/2013
Radiation protection	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2009 to 6/30/2013
Mathematics pertaining to the use and measurement of radioactivity	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2009 to 6/30/2013
Chemistry of byproduct material for medical use	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2009 to 6/30/2013
Radiation biology	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2009 to 6/30/2013
Total Hours of Training:		<input type="text" value="200"/>	

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: 35	
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	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2/1/16 to 4/1/16
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2/1/16 to 4/1/16
Calculating, measuring, and safely preparing patient or human research subject dosages	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2/1/16 to 4/1/16
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2/1/16 to 4/1/16
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Karmanos Cancer Center NRC #21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2/1/16 to 4/1/16

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
Nitin Vaishampayan, M.D.	21-04127-06

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.

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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
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	2/29/16: 200.34 uCi 3/16/16: 134.7 uCi 3/18/16: 119.47 uCi	Karmanos Cancer Center/21-04127-06	2/7/16 to 4/15/16
Parenteral administration of any other radionuclide for which a written directive is required <div style="border: 1px solid black; height: 30px; width: 100%;"></div> (List radionuclides)			

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 Peter Paximadis, M.D. 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 Nitin Vaishampayan, M.D.	Signature 	Telephone Number (313) 503-2456	Date 6/3/16
License/Permit Number/Facility Name Karmanos Cancer Center/21-04127-06			

Taylor, Tiresha

From: Forster, Sara
Sent: Monday, June 06, 2016 7:39 AM
To: Taylor, Tiresha
Subject: FW: RE: Additional Information Request re Amendment Requests for Karmanos Cancer Center, NRC License No. 21-04127-06, CN590716/CN590749
Attachments: 10 CFR 35.300 AU_Additional Info_Dominello.pdf; 10 CFR 35.300 AU_Additional Info_Paximadis.pdf

Please scan in attached letters and return to me. Thank you so much! - Sara

From: Masi, Kathryn [mailto:masik@karmanos.org]
Sent: Friday, June 03, 2016 9:45 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Cc: Rakowski, Joseph <rakowski@karmanos.org>
Subject: [External_Sender] RE: Additional Information Request re Amendment Requests for Karmanos Cancer Center, NRC License No. 21-04127-06, CN590716/CN590749

Dear Ms. Forster,

I am writing on behalf of Joe Rakowski. Please find attached the additional information requested in your 6/1/2016 email concerning the authorized user amendment request for Drs. Dominello and Paximadis.

Sincerely,

Kathryn Masi, MS
Medical Physicist
Karmanos Cancer Center
Gershenson Radiation Oncology Center
4100 John R
Detroit, MI 48201
Office: (313)576-9613

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Wednesday, June 01, 2016 4:52 PM
To: Rakowski, Joseph
Subject: Additional Information Request re Amendment Requests for Karmanos Cancer Center, NRC License No. 21-04127-06, CN590716/CN590749

Dear Mr. Rakowski:

In your letters dated April 20, 2016, and April 11, 2016, you requested to add 10 CFR 35.300 authorizations (limited to radium-223) for Authorized Users (AUs) Peter Paximadis, M.D., and Michael Dominello, M.D., respectively. We have noted that you provided an NRC Form 313A (AUT) Nitin Vaishampayan, M.D., as a trainer and preceptor for each proposed 10 CFR 35.300 Authorized User (AU). However, the forms are unclear as to (1) the number of hours of work experience each AU has had in the use of 10 CFR 35.300 material since the licensee and preceptor/trainer have been authorized for use of 10 CFR 35.300 material; (2) the radioactive quantities and dates of administration for each of the 3 cases in which each of the two AUs participated in parenteral radium-223 administrations at your facility; and (3) the preceptor attestation as to the AUs' abilities to independently administer 10 CFR 35.390(b)(1)(ii)(G)(3) material. (Note that the NRC

considers radium-223 to fall under (G)(3) and not (G)(4). This is because, even though it is administered primarily for the alpha-emitting properties, radium-223 also is classified as a "photon-emitting radionuclide with a photon energy less than 150 keV.") Accordingly, we have reviewed your requests, and need the following additional information to add each proposed 10 CFR 35.300 AU:

1. Please resubmit page 2 of each submitted NRC Form 313A(AUT). In the section 3.b., "Supervised Work Experience," table, please include the total hours of experience for Dr. Paximadis, from February 1, 2016 through April 1, 2016, and for Dr. Dominello, from November 15, 2015 through March 31, 2016.
2. Please resubmit page 3 of each submitted NRC Form 313A(AUT). In the section 3.b., "Supervised Work Experience," table (continued), please revise to indicate the 10 CFR 35.390(b)(1)(ii)(G)(3) material use experience, "parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy of less than 150 keV requiring a written directive is required." In the section 3.c., "Supervised Clinical Experience" table, please list the radioactive quantities and administration dates for Dr. Paximadis from February 17, 2016 through April 15, 2016, and for Dr. Dominello, from February 1, 2016 through April 1, 2016. Note that the submitted cases should be moved to the third row. This is the one associated with the 10 CFR 35.390(b)(1)(ii)(G)(3) authorization.
3. Please resubmit page 6 of each submitted NRC Form 313A(AUT). In the "Fourth section" at the top of the page, please confirm that the preceptor attestations apply to the 10 CFR 35.390(b)(1)(ii)(G)(3), "parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy of less than 150 keV requiring a written directive as required," for both Dr. Paximadis and Dr. Dominello.

Please submit additional information on or before close of business on Thursday, June 16, 2016. Additional guidance may be found in NUREG 1556, Vol. 9, rev. 2, "Program Program-Specific Guidance About Medical Use Licenses," which may be found at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2>

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Any response must be submitted under a signed and dated cover letter. Please call me to confirm receipt of this email. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892



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