

BARBARA ANN
KARMANOS
CANCER CENTER
At the Detroit Medical Center

April 11, 2016

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

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

Dear Reviewer,

This letter is a request for Authorized User status for Michael Dominello, D.O. for 10 CFR 35.300, limited to parenteral administration of radium-223. The NRC Form 313A (AUT) is attached.

Also, please correct our mistake on the license of specifying his medical degree as M.D. It should be D.O.

If you require further information please feel free to contact our RSO Joe Rakowski at (313)576-9616. Thank you.

Sincerely,



Mara Jelich
Executive Director, Radiation Oncology and Imaging
Karmanos Cancer Center
4100 John R St., Mail Code GE00RO
Detroit, MI 48201

Enclosure: NRC Form 313A (AUT)

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



RECEIVED APR 11 2016

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|--|--|---|--|---|--|
| NRC FORM 313A (AUT) (05-2012) | | U.S. NUCLEAR REGULATORY COMMISSION | | APPROVED BY OMB: NO. 3150-0120 EXPIRES: (05/31/2015) | |
| 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] | | | | | |
| Name of Proposed Authorized User Michael Dominello, D.O. | | State or Territory Where Licensed MI | | | |
| Requested Authorization(s) (check all that apply): <input type="checkbox"/> 35.300 Use of unsealed byproduct material for which a written directive is required OR <input type="checkbox"/> 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) <input type="checkbox"/> 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> 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 <input checked="" type="checkbox"/> 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) | | | | | |
| <p>* 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.</p> <p><input type="checkbox"/> 1. Board Certification</p> <p style="margin-left: 20px;">a. Provide a copy of the board certification.</p> <p style="margin-left: 20px;">b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.</p> <p style="margin-left: 20px;">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.</p> <p style="margin-left: 20px;">d. Skip to and complete Part II Preceptor Attestation.</p> <p><input checked="" type="checkbox"/> 2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization</p> <p style="margin-left: 20px;">a. Authorized User on Materials License <u>NRC 21-04127-06</u> under the requirements below or equivalent Agreement State requirements (check all that apply):</p> <p style="margin-left: 40px;"><input type="checkbox"/> 35.390 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input type="checkbox"/> 35.490 <input checked="" type="checkbox"/> 35.690</p> <p style="margin-left: 20px;">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.</p> <p style="margin-left: 20px;">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.</p> | | | | | |

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

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ 3. Training and Experience for Proposed Authorized Usera. 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 <u>Residency</u> | 40 | June 1, 2011 - June 30, 2015 |
| Radiation protection | Wayne State University/Karmanos Cancer Center <u>Residency</u> | 40 | June 1, 2011 - June 30, 2015 |
| Mathematics pertaining to the use and measurement of radioactivity | Wayne State University/Karmanos Cancer Center <u>Residency</u> | 40 | June 1, 2011 - June 30, 2015 |
| Chemistry of byproduct material for medical use | Wayne State University/Karmanos Cancer Center <u>Residency</u> | 40 | June 1, 2011 - June 30, 2015 |
| Radiation biology | Wayne State University/Karmanos Cancer Center <u>Residency</u> | 40 | June 1, 2011 - June 30, 2015 |
| Total Hours of Training: | | 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: 500 | |
|--|---|--|--------------------------------|
| 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 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 | June 1, 2011 to March 31, 2016 |
| | Karmanos Cancer Center NRC#21-04127-06 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | June 1, 2011 to March 31, 2016 |
| 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 | June 1, 2011 to March 31, 2016 |
| 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 | June 1, 2011 to March 31, 2016 |
| 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 | June 1, 2011 to March 31, 2016 |

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

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 Experience (continued)

| | |
|---|--|
| Supervising Individual | License/Permit Number listing supervising individual as an authorized user |
| Nitin Vaishampayan, M.D. | NRC#21-04127-06 |
| Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**: | |
| <input type="checkbox"/> 35.390 | With experience administering dosages of: |
| <input type="checkbox"/> 35.392 | <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) |
| <input type="checkbox"/> 35.394 | <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) |
| <input checked="" type="checkbox"/> 35.396 | <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required |
| | <input checked="" type="checkbox"/> 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 | | | |
| Parenteral administration of any other radionuclide for which a written directive is required <div style="border: 1px solid black; padding: 2px; width: fit-content;">Ra-223</div> <div style="text-align: center; font-size: small;">(List radionuclides)</div> | 3 | Karmanos Cancer Center/NRC#21-04127-06 | Feb 1, 2016 to April 1, 2016 |

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

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

Nitin Vaishampayan, M.D.

NRC#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.

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 _____ 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)
(05-2012)

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 _____ 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)
(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 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) 593-7667 | Date 4/11/16 |
| License/Permit Number/Facility Name NRC#21-04127-06/Karmanos Cancer Center | | | |



CANCER CENTER

At the Detroit Medical Center

FAX

DATE: 4/11/2016

TO: NRC Region III

FAX NUMBER: 630-515-1078

FROM: Joe Rakowski 313-576-9616

RE: Amendment request

NUMBER OF PAGES (Including cover sheet): 8
