

American Oncologic Association of Michigan, P.C.
d/b/a 21st Century Oncology of Michigan

February 16, 2017

Licensing Assistance Team
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Radioactive materials License # 21-26488-01
Control Number # 592375

Dear Colleen Carol Casey,

In reference to your phone an email conversation with our Chief Physicist Teamour Nurushev, PhD, DABR, please find enclosed a revised preceptor attestation form to request authorization for Dr. John Vito Antonucci for Radium-223 as permitted by 10 CFR 35.300.

Should you have any questions, please feel free to contact me at 239-736-7377

Sincerely,

A handwritten signature in black ink, appearing to read "L. Kestin", with a stylized flourish at the end.

Larry Kestin, M.D.
Radiation Safety Officer

**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

John Vito Antonucci, M.D.

State or Territory Where Licensed

State of Michigan

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 NRC License # 21-26488-01 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	NRC License # 21-26488-01	16	September 2016
Radiation protection	NRC License # 21-26488-01	16	September 2016
Mathematics pertaining to the use and measurement of radioactivity	NRC License # 21-26488-01	16	September 2016
Chemistry of byproduct material for medical use	NRC License # 21-26488-01	16	September 2016
Radiation biology	NRC License # 21-26488-01	16	August 2016
Total Hours of Training:		80	

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: 20	
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	NRC License # 21-26488-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	August-November, 2016
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	NRC License # 21-26488-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	August-November, 2016
Calculating, measuring, and safely preparing patient or human research subject dosages	NRC License # 21-26488-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	August-November, 2016
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	NRC License # 21-26488-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	August-November, 2016
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	NRC License # 21-26488-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	August-November, 2016

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

Mihai Ghilezan, M.D.

License/Permit Number listing supervising individual as an authorized user

NRC License # 21-26488-01

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			
Parenteral administration of any other radionuclide for which a written directive is required <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">Ra-223 (Xofigo)</div> (List radionuclides)	3	NRC License # 21-26488-01	October - November, 2016

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
Mihai Ghilezan, M.D.	NRC License # 21-26488-01

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 checked="" 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.

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

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 John Vito Antonucci, 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 John Vito Antonucci, 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

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 John Vito Antonucci, 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 Mihai Ghilezan, M.D.	Signature <i>Mihai Ghilezan</i>	Telephone Number 248-835-7253	Date 2/15/17
License/Permit Number/Facility Name NRC License # 21-26488-01			

Casey, Colleen

From: Nurushev, Teamour S. <Teamour.Nurushev@21co.com>
Sent: Thursday, February 16, 2017 10:51 AM
To: Casey, Colleen
Subject: [External_Sender] RE: RE: Test message for 592375 response
Attachments: Transmittal letter control 592375.pdf; nrc313a(aut) Antonucci-sign.pdf

Dear Colleen,
Please find attached the transmittal letter a corrected license amendment application.
Hopefully the corrections are satisfactory.
Thank you,
Tim.

Confidentiality Statement:

This email and any files transmitted with it may contain confidential and/or privileged material and is intended only for the person or entity to which it is addressed.

Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited.

If you have received this email in error, please notify the sender immediately and delete this material from all known records.

Thank you

From: Casey, Colleen [mailto:Colleen.Casey@nrc.gov]
Sent: Wednesday, February 15, 2017 5:02 PM
To: Nurushev, Teamour S.
Subject: RE: RE: Test message for 592375 response

This is still incomplete and lacking the signed transmittal letter we talked about. Call me if you want to discuss.

(Please address me as "Colleen")

Colleen Carol Casey, Colleen.Casey@nrc.gov

Materials Licensing Reviewer

U.S. Nuclear Regulatory Commission

Region III

2443 Warrenton Road

Suite 210

Lisle, IL 60532-4352

Colleen.Casey@nrc.gov

(630) 829-9841 Direct, Central time zone

(630) 515-1078 Best Fax No., to our IM Center

NRC 24 HR Operations Center

(301) 816-5100 (Eastern time zone)

Gentle Reminders: Unless previously arranged with or requested by me directly, please do *not* submit any unsolicited licensing requests, responses or correspondence via e-mail.

Please only submit *one complete, physically and legibly signed* copy of your correspondence to us. "Draft" and/or unsigned documents will not be accepted.

Please prepare your licensing requests in accordance with NUREG 1556 Series Guidance at:

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

Thank you very much!

Please also note that my full-time work schedule includes every other Friday off.

Ensuring the health and safety of
our people, our nation and
our environment

<http://www.nrc.gov/>



From: Nurushev, Teamour S. [<mailto:Teamour.Nurushev@21co.com>]

Sent: Wednesday, February 15, 2017 4:00 PM

To: Casey, Colleen <Colleen.Casey@nrc.gov>

Subject: [External_Sender] RE: Test message for 592375 response

Hi Colleen,

It was nice talking to you today! Thank you for the information and clarifications.

Please find attached edited and re-signed form. Hopefully it is better this time.

I will relay our conversation to the corporate office to make sure the future submissions are checked prior to submission.

Best regards,
Tim.

Teamour (Tim) Nurushev, PhD, DABR.
Regional Director, Physics
21st Century Oncology of Michigan
Teamour.Nurushev@21co.com
248-410-8011 cell.

From: Casey, Colleen [<mailto:Colleen.Casey@nrc.gov>]

Sent: Wednesday, February 15, 2017 4:09 PM

To: Nurushev, Teamour S.

Subject: Test message for 592375 response

Thanks for your time today, Tim, information below should be helpful. Give me a call or shoot me an email if you have a question. Thanks very much.

(Please address me as "Colleen")

Colleen Carol Casey, Colleen.Casey@nrc.gov

Materials Licensing Reviewer

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