March 12 2018

Materials Licensing Branch

U. S. Nuclear Regulatory Commission

Region III

2443 Warrenville Road, Suite 210

Lisle, Illinois 60532 – 4352

To whom it may concern

This letter is to request an amendment to the NRC byproduct materials license **# 21-01492-02,** Covenant Medical Center, Inc – Saginaw, Michigan.

Submitted is form 313A(AUT) in support of **Mark Zaki MD** to be added to the license as an authorized user under 35.396 for Parenteral administration of radionuclides. If you have any need of further information or questions please contact our physicist Ian Reineck at 989-392-7700 or ireineck@chs-mi.com.

Sincerely

Ian B Reineck MS DABR

Medical Physicist

NRC FORM 313A (AUT)
(06-2016)

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: 06/30/2019

Name of Proposed Authorized User	State or Territory Where Licensed
Mark, Zaki,	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 21-01492-02 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	7/1/2013 to 6/30/2017
Radiation protection	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2013 to 6/30/2017
Mathematics pertaining to the use and measurement of radioactivity	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2013 to 6/30/2017
Chemistry of byproduct material for medical use	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2013 to 6/30/2017
Radiation biology	Wayne State University/Karmanos Cancer Center Medical Residency	40	7/1/2013 to 6/30/2017
	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:** 40

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 Harper Hospital NRC #21-04127-02	☑ Yes ☐ No	7/1/2013 to 6/30/2017
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 Harper Hospital NRC #21-04127-02	☑ Yes ☐ No	7/1/2013 to 6/30/2017
Calculating, measuring, and safely preparing patient or human research subject dosages	Karmanos Cancer Center NRC #21-04127-06 Harper Hospital NRC #21-04127-02	☑ Yes ☐ No	7/1/2013 to 6/30/2017
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Karmanos Cancer Center NRC #21-04127-06 Harper Hospital NRC #21-04127-02	☑ Yes ☐ No	7/1/2013 to 6/30/2017
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Karmanos Cancer Center NRC #21-04127-06 Harper Hospital NRC #21-04127-02	☑ Yes ☐ No	7/1/2013 to 6/30/2017

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
- ☐ 35.394
- ☑ 35.396
  - ☐ 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.

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	Ra-223 chloride: 6	Karmanos Cancer Center/21-04127-06	3/16/16, 1/13/17, 2/3/17, 2/8/17, 2/10/17, 3/17/17
Parenteral administration of any other radionuclide for which a written directive is required (List radionuclides)			

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
☐ 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.

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
Name of Proposed Authorized User

requirements in 35.390(a)(1).

OR

Training and Experience

☑ I attest that Mark Zaki, M.D. 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 Mark Zaki, 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 Mark Zaki, 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) (05-2012) Ra-223 chloride 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 Mark Zaki MD (Name of Proposed Authorized User) is an authorized user under 10 CFR 35.490 or 35.690 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the board certification 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 Ra-223 chloride

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Nitin Vaishampayan, M.D.	NV	(313) 503-2456	6/28/17

License/Permit Number/Facility Name

Karmanos Cancer Center/21-04127-06

Sandrik, Lauren

From: Forster, Sara
Sent: Monday, March 12, 2018 1:38 PM
To: Pavon, Sandy; Sandrik, Lauren; Song, Taehoon
Cc: Tomczak, Tammy
Subject: FW: Additional Information request for Covenant Medical Center, Inc., Lic. 21-01492-01, CN600439
Attachments: Zaki license amendment.pdf

Please scan in and return to me. This is a new licensing action that will need to be assigned.

From: Ian Reineck [mailto:IReineck@chs-mi.com]
Sent: Monday, March 12, 2018 1:31 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: RE: RE: Additional Information request for Covenant Medical Center, Inc., Lic. 21-01492-01, CN600439

Here is the revised form. Thank you so much for your help!

Ian

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Monday, March 12, 2018 12:04 PM
To: Ian Reineck <IReineck@chs-mi.com>
Subject: RE: RE: RE: Additional Information request for Covenant Medical Center, Inc., Lic. 21-01492-01, CN600439

Would 1 pm central work for you? Please call me then, or let me know the number you would like me to call.

Sincerely,

Sara Forster
U.S. NRC

From: Ian Reineck [mailto:IReineck@chs-mi.com]
Sent: Monday, March 12, 2018 10:38 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: RE: Additional Information request for Covenant Medical Center, Inc., Lic. 21-01492-01, CN600439

I would like to continue the process of getting Dr Mark Zaki on our license for Xofigo. Are you available for a phone call today? I've left a couple voicemails over the last few weeks.

Thanks
Ian Reineck

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Friday, September 29, 2017 9:53 AM
To: Ian Reineck <IReineck@chs-mi.com>
Subject: RE: RE: Additional Information request for Covenant Medical Center, Inc., Lic. 21-01492-01, CN600439

One other thing regarding signatures... Since you are the listed contact person in the initial amendment request, the NRC will accept your signature on the additional information letter (including the request to withdraw-in-part). Hopefully this helps.

Sara Forster

From: Ian Reineck [mailto:IReineck@chs-mi.com]
Sent: Thursday, September 28, 2017 2:22 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: Additional Information request for Covenant Medical Center, Inc., Lic. 21-01492-01, CN600439

Dear Ms Forster

I'm sorry I haven't had a chance to get back to you. Are you available tomorrow morning for a phone call? The Dr is wondering if he can perform HDR duties at least since it sounded like from our last phone call that you said he was good on the front.

Thanks

Ian

PS my cell is 989-392-7700

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Friday, September 15, 2017 10:29 AM
To: Ian Reineck <IReineck@chs-mi.com>
Subject: Additional Information request for Covenant Medical Center, Inc., Lic. 21-01492-01, CN600439

Dear Mr. Reineck:

We have received and reviewed an August 7, 2017 letter (ML17226A236) from the above referenced licensee's Senior Vice President Dan George requesting an amendment to the above referenced license, removing Victor Hosfeld, M.S., as an Authorized Medical Physicist (AMP) and adding a new Authorized User (AU) Mark Zaki, M.D. with authorizations for 10 CFR 35.300 (including both parenteral and oral administrations), 10 CFR 35.400, and 10 CFR 35.600 (limited to iridium-192 in an HDR).

Please note that, for 10 CFR 35.300 use, authorizations will always be limited to those the licensee both requests and provides adequate documentation for. During our review, we have identified items supporting the

request for Dr. Zaki's 10 CFR 35.300 authorization needing additional supporting documentation or clarification. Accordingly, prior to continuing our review, we need additional information from you responding to the items listed below:

The submitted NRC Form 313A (AUT) included separate preceptor attestations for Dr. Hosfeld's qualifications for oral sodium iodide I-131 administrations and parenteral administrations of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV. In addition, the supporting cases include yttrium-90 microspheres. It is unclear whether supporting yttrium-90 cases were completed under 10 CFR 35.300 (unsealed radiopharmaceutical) or under 10 CFR 35.1000 (microspheres).

If two separate preceptor attestations (one for oral I-131 and one for parenteral administrations) are submitted in support of the request, please submit two full NRC Form 313A (AUT) forms, documenting all elements of either 10 CFR 35.390, 35.392, 35.394, or 35.396, as applicable. Each form should be clear as to:

1. Whether information submitted in support of Dr. Zaki's request is meant to fulfill 10 CFR 35.390, 35.392, 35.394, and/or 35.396 requirements for a 10 CFR 35.300 AU;

2. Total Hours of Dr. Zaki's supervised work experience under <u>each</u> listed supervising AU at each listed institution;

    - Note: the total hours listed for any one attestation must meet the requirements in 10 CFR 35.390, 35.392, 35.394, or 35.396. Supervised work experience hours required under 10 CFR 35.390 are significantly greater than those required under the other listed sections.

3. For submitted sodium iodide I-131 administrations provided in support of the request, the dates and radioactive quantities of sodium iodide I-131 administered by Dr. Zaki under a qualified AU;

4. For submitted yttrium-90 administrations, please confirm that those administrations were performed under 10 CFR 35.300 and were not administrations of microspheres.

    - Note: Yttrium-90 microspheres are considered emerging technology, and are authorized using criteria specified in 10 CFR 35.1000 guidance. Those cases may not be used in support of requests for approvals of 10 CFR 35.300 material.

5. For each submitted form, please provide written attestation that Dr. Zaki has satisfactorily completed the requirements in 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394 and/or 10 CFR 35.396, as applicable to that attestation. You may do this using the current NRC Form 313A (AUT). If the supervising AU is not listed on an NRC license, supporting documentation showing that the supervising AU is qualified would also be needed. For example if the preceptor and supervising individual Richard Joyrich, M.D. is used, please include a signed and dated letter from the RSO or RSC Chairperson for NRC Lic. No. 21-04127-02 confirming that this physician is or was listed as AU on that license at the dates of the supervised experience and of the attestation.

Please provide the requested information within 14 days of this message (by close of business on Thursday, September 29, 2017). For any item to which you will be unable to respond in full, please indicate whether you wish to withdraw your request for the 10 CFR 35.300 authorizations for Dr. Zaki or the date by which requested information will be submitted. Include a signed and dated cover letter transmitting your response.

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Please call me to follow up on this request and with any questions you may have.

Sincerely yours,

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
Facsimile: (630) 515-1078

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