Roldan, Lizette

From: Roldan, Lizette
Sent: Tuesday, June 17, 2014 10:02 AM
To: 'avanterpool@krmc.org'
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING LICENSE AMENDMENT, CONTROL 583503

Importance: High

License No.: 25-15463-01
Docket No.: 030-09152
Control No.: 583503

Dear Mr. Vanterpool:

This is in reference to your letter dated March 20, 2014 requesting to amend Nuclear Regulatory Commission License Number 25-15463-01. In order to continue our review, we need the following additional information:

1. In order to add Dr. Pomerantz for 35.300, the form submitted must name the supervising individual and their qualifications. Sections 3b, and 3c, of pages 3 and 4, respectively of the NRC Form 313A (AUT) should have included the information of the supervising individual's name, license number and qualifications. Resubmit a completed NRC Form 313A (AUT) for Dr. Pomerantz.

2. To add Dr. Benedetto and Dr. Friedman as authorized users for 35.1000 for I-125 seed implantation, please provide a signed letter by Dr. Stillie confirming that in addition to reviewing the radiation safety items listed on his letters dated March 10, 2014 for Dr. Friedman, and March 12, 2014 for De. Benedetto, both Dr. Friedman and Dr. Benedetto have work experience on each of those bulleted items, in addition to work experience for ordering, receiving, and the safely unpacking of radioactive material for each of the 3 cases.

We will continue our review upon receipt of this information. You may respond by email attachment in PDF format. In your response, refer to Mail Control No. 583503. If you have any technical questions regarding this deficiency letter, please call me at (817) 200-1596.

Please reply to this request by tomorrow, June 18, 2014.

Thanks,

Lizette Roldán-Otero, Ph.D.
US NRC Region IV – NMSB-B
1600 Lamar Blvd
Arlington, TX 76011
Office: 817-200-1596
Fax: 817-200-1188

PUBLIC
☐ Immediate Release
☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: LRO Date: 6/18/14

KALISPELL REGIONAL HEALTHCARE
Radiation Oncology

RECEIVED
JUN 18 2014
DNMS

June 17, 2014

To Whom It May Concern:

This letter should serve as documentation of supervised clinical case experience for William Benedetto, MD performing radioactive seed localization (RSL) of non-palpable breast lesions with I-125 seeds. Dr. Benedetto is a board certified radiologist and an authorized used listed on Kalispell Regional Medical Center's license, number 25-15463-01. I observed Dr. Benedetto perform 3 implants of breast lesions. I witnessed patients P.N. on 1/21/14, A.W. on 3/12/14, and R.B. on 3/12/14. I instructed Dr. Benedetto in the proper techniques for safe handling of the seeds, appropriate preparation, as well as seed deployment. We reviewed radiation safety relative to the use of I-125 seeds for localization including but not limited to:

- Performing the related surveys using appropriate instrumentation;
- Preparing, implanting and safely removing RSL sources safely, to include the use of remote handling tools to manipulate seeds and the proper use of shields;
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a leaking or broken source;
- Emergency procedures, such as regarding broken or leaking seeds;
- Reviewing and understanding the administrative controls in place to prevent a medical event; and
- Maintaining running inventories of radioactive material on hand.
- Has work experience on each of the above bulleted items, in addition to work experience for ordering, receiving, and the safely unpacking of radioactive material for each of the 3 above named cases.

Dr. Benedetto has gained the competency to perform these procedures independently.

Sincerely,

Gordon Donald Stillie, DO, MS, MBA, FACRO

343 Sunnyview Lane, Kalispell, MT 59901
(406)752-1790 Phone * (406)756-3529 Fax

KALISPELL REGIONAL HEALTHCARE
Radiation Oncology

June 17, 2014

To Whom It May Concern:

This letter should serve as documentation of supervised clinical case experience for Richard Friedman, MD performing radioactive seed localization (RSL) of non-palpable breast lesions with I-125 seeds. Dr. Friedman is a board certified radiologist and an authorized user listed on Kalispell Regional Medical Center's license, number 25-15463-01. I observed Dr. Friedman perform 3 implants of breast lesions. I witnessed patients L.N. on 1/9/14, R.G. on 1/9/14, and W.K. on 3/10/14. I instructed Dr. Friedman in the proper techniques for safe handling of the seeds, appropriate preparation, as well as seed deployment. We reviewed radiation safety relative to the use of I-125 seeds for localization including but not limited to:

- Performing the related surveys using appropriate instrumentation;
- Preparing, implanting and safely removing RSL sources safely, to include the use of remote handling tools to manipulate seeds and the proper use of shields;
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a leaking or broken source;
- Emergency procedures, such as regarding broken or leaking seeds;
- Reviewing and understanding the administrative controls in place to prevent a medical event; and
- Maintaining running inventories of radioactive material on hand.
- Has work experience on each of the above bulleted items, in addition to work experience for ordering, receiving, and the safely unpacking of radioactive material for each of the 3 above named cases.

Dr. Friedman has gained the competency to perform these procedures independently.

Sincerely,

Gordon Donald Stillie, DO, MS, MBA, FACRO

343 Sunnyview Lane, Kalispell, MT 59901
(406)752-1790 Phone * (406)756-3529 Fax

NRC FORM 313A (AUT) (05-2012) 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: (05/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
Benjamin Pomerantz, MD	Montana

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.

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
	Total Hours of Training: ☐		

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:**		
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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

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
RICHARD FRIEDMAN, MD	LICENSE # 25-15463-01 AU 35.300 MTMD, MEDPHYSLIC # 10234

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.

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)	3	Kalispell Regional Medical Center	1/18/2013 4/1/2013 (2)
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 (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
RICHARD FRIEDMAN, MD	LICENSE # 25-15463-01 AV 35300 MTMD MEDPHYSICS # 10234

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 Benjamin Pomerantz, MD (Name of Proposed Authorized User) has satisfactorily completed the training and experience requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ (Name of Proposed Authorized User) 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).

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 Benjamin Pomerantz, MD 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 Benjamin Pomerantz, MD 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 _____ 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	Signature	Telephone Number	Date
Richard Friedman		(406) 752-1770	03/19/2014

License/Permit Number/Facility Name
25-15463-01 Kalispell Regional Medical Center