

Sara Forster

From: Sara Forster
Sent: Friday, November 25, 2022 4:36 PM
To: Ray Carlson; info@pinnacleheart.com
Cc: mufeed.otaibey@versantphysics.com
Subject: Additional Information needed re Amendment to Pinnacle Heart Specialists, LLC, NRC License No. 21-32775-01, CN633476
Attachments: 02201.633476.13-32775-01 RFAI email attachment NRC Form 313A(RSO)_ML12164A742_Dated Jan 2020.pdf

Good afternoon, Dr. Akinwande and Mr. Carlson:

Our office is in receipt of the October 24, 2022, letter requesting to list Mufeed M. Al-Otaibey, M.S., as the Radiation Safety Officer (RSO) on the referenced license. Regarding Mr. Al-Otaibey's training and experience, it is unclear from the submitted materials how the NRC's regulatory requirements in [Title 10 of the Code of Federal Regulations \(10 CFR\) Section 35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer,"](#) are met. Regarding the Mr. Al-Otaibey's Training and Experience, it will be most expedient to use NRC's [Form 313A \(RSO\), "Radiation Safety Officer or Associate Radiation Safety Officer Training, Experience, and Preceptor Attestation,"](#) to indicate whether and how the proposed RSO meets the requirements in either [10 CFR 35.50\(a\)](#), [35.50\(b\)](#), [35.50\(c\)\(1\)](#), or [35.50\(c\)\(2\)](#).

Specifically, regarding the request, please provide the following information regarding the proposed RSO's qualifications, as requested in NRC's [NUREG 1556, Volume 9, revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses,"](#) dated September 2019:

- a. If qualifications include a specialty board certification accepted as noted at the NRC's ["Specialty Board Certifications Recognized by NRC Under 10 CFR Part 35" website](#), please attach a copy of that certification.
- b. If qualifications include a structured educational program, please list:
 - (i) the name and location where required classroom and laboratory training was completed, as well as total hours of training in the topics listed in 10 CFR 35.50(b)(1)(i);
 - (ii) the licensee's name, facility location, experience dates, supervising individuals, and License or Permit number, for the topics listed in 10 CFR 35.50(b)(1)(ii); and
 - (iii) written attestation, signed by a qualified preceptor RSO, including that preceptor RSO's name and License or Permit number.
- c. For all cases, the training in 10 CFR 35.200 related radiation safety, regulatory issues, and emergency procedures also must be listed, including dates, licensee information for the facility where the training information was completed, and the name of the RSO or Authorized User (AU) who supervised that training.

If the proposed RSO does not meet the training and experience requirements stipulated in 10 CFR 35.50 please let us know as soon as possible, so that we may evaluate whether to close your request.

The regulatory 10 CFR 35.50 requirement for RSO experience, the NRC's medical guidance, and the NRC's Form 313A (RSO) may be found at the NRC's website at <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0050.html>, <https://www.nrc.gov/docs/ML1925/ML19256C219.pdf> and <https://www.nrc.gov/docs/ML1216/ML12164A742.pdf>, respectively.

Please provide a response via a signed and dated letter within 14 days of this request for this information (on or before December 9, 2022). If you are unable to provide a response before then, please provide a signed and dated letter by that date indicating the date by which you will be able to provide a written response to the items outlined in this request. For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me by phone or email.

Sincerely yours,

Sara A. Forster, Health Physicist

U.S. Nuclear Regulatory Commission - Region III

Division of Radiological Safety & Security

Materials Licensing Branch

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**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.57, 35.50]**

Name of Individual RSO ARSO

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100 35.200 35.300 35.400 35.500 35.600 (remote afterloader)
- 35.600 (teletherapy) 35.600 (gamma stereotactic radiosurgery) 35.1000 (_____)

**PART I -- TRAINING AND EXPERIENCE
(Select one of the five 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 obtained 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. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.50;
 - (i) Go to the table in 5c and describe training provider and dates of training for each type of use for which authorization is sought.
 - (ii) Stop here
- c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57 (a)(2);
 - (i) Provide documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;
 - (ii) Stop here

OR

2. Current Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) Seeking Authorization to Be Recognized as a RSO or ARSO for the Additional Medical Uses Checked Above

- a. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO or ARSO is sought.
- b. If board certified, provide a copy of the certificate and stop here. If not board certified, skip to and complete Part II Preceptor Attestation.

OR

3. Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) identified on a license or permit in accordance with 10 CFR 35.50 (c)(2)

- a. Provide license number.
- b. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. If board certified, provide a copy of the certificate and stop here. If not board certified, skip to and complete Part II Preceptor Attestation.

OR

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)**

4. Individuals applying simultaneously to be the RSO and AU on a new license

- a. Documentation of training and experience to be a new AU is attached
- b. The new license application is attached.
- c. Stop here.

OR

5. Structured Educational Program for Proposed RSO or ARSO

a. Classroom and Laboratory Training

| 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 | | | |
| Radiation biology | | | |
| Radiation dosimetry | | | |

Total Hours of Training:

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)**

5. Structured Educational Program for Proposed RSO or ARSO (continued)

b. Supervised Radiation Safety Experience

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

| Description of Experience | Location of Training/ License or Permit Number of Facility | Dates of Training* |
|---|---|-----------------------|
| Shipping, receiving, and performing related radiation surveys | | |
| Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides | | |
| Securing and controlling byproduct material | | |
| Using administrative controls to avoid mistakes in administration of byproduct material | | |
| Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures | | |
| Using emergency procedures to control byproduct material | | |
| Disposing of byproduct material | | |
| Licensed Material Used (e.g., 35.100, 35.200, etc.)+ <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div> | | |

+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)**

5. Structured Educational Program for Proposed RSO or ARSO (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

| | |
|---|--|
| Supervising Individual | License/Permit Number listing supervising individual as a Radiation Safety Officer or Associate Radiation Safety Officer |
| The supervising individual is authorized as the _____ for the following medical uses: | |
| <input type="checkbox"/> 35.100 | <input type="checkbox"/> 35.200 |
| <input type="checkbox"/> 35.500 | <input type="checkbox"/> 35.600 (remote afterloader) |
| <input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery) | <input type="checkbox"/> 35.1000 (_____) |
| <input type="checkbox"/> 35.300 | <input type="checkbox"/> 35.400 |
| | <input type="checkbox"/> 35.600 (teletherapy) |
| <input type="checkbox"/> Radiation Safety Officer or the <input type="checkbox"/> Associate Radiation Safety Officer | |

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license for the RSO or types of use for which the ARSO will be listed on the license.

| Description of Training | Training Provided By | Dates of Training* |
|---|----------------------|--------------------|
| Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.300 uses | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.400 uses | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s): | | |

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)**

5. Structured Educational Program for Proposed RSO or ARSO (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

| | |
|---|--|
| Supervising Individual <i>If training was provided by supervising RSO, ARSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</i> | License/Permit Number listing supervising individual |
| License/Permit lists supervising individual as: | |
| <input type="checkbox"/> Radiation Safety Officer <input type="checkbox"/> Associate Radiation Safety Officer <input type="checkbox"/> Authorized User <input type="checkbox"/> Authorized Nuclear Pharmacist <input type="checkbox"/> Authorized Medical Physicist | |
| Authorized as RSO, ARSO, AU, ANP, or AMP for the following medical uses: | |
| <input type="checkbox"/> 35.100 <input type="checkbox"/> 35.200 <input type="checkbox"/> 35.300 <input type="checkbox"/> 35.400 <input type="checkbox"/> 35.500 <input type="checkbox"/> 35.600 (remote afterloader) <input type="checkbox"/> 35.600 (teletherapy) <input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery) <input type="checkbox"/> 35.1000 (_____) | |

d. Skip to and complete 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.

First Section

Structured Educational Program for Proposed RSO or ARSO

I attest that _____ has satisfactorily completed
Name of Proposed RSO/ARSO
 a structural educational program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

AND

Second Section

I attest that _____ has training in
Name of Proposed RSO/ARSO
 radiation safety, regulatory issues, and emergency procedures for the following types of use:

Check all that apply:

- 35.100 35.200
- 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
- 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
- 35.300 Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)**

PART II – PRECEPTOR ATTESTATION (continued)

Check all *that apply*:

- 35.400
- 35.500
- 35.600 remote afterloader units
- 35.600 teletherapy units
- 35.600 gamma stereotactic radiosurgery units
- 35.1000 emerging technologies, including:

Third Section

AND

I attest that

Name of Proposed Radiation Safety Officer or Associate Radiation Safety Officer

is able to independently fulfill the radiation safety-related duties as:

A Radiation Safety Officer for a medical use licensee.

OR

An Associate Radiation Safety Officer for a medical use licensee.

Fourth Section

Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for

I am the Associate Radiation Safety Officer for

Name of Facility: _____

License/Permit Number: _____

Name of Preceptor (Typed or printed)

Telephone Number

Date

Signature