

From: [Seeley, Shawn](#)
To: [Reyes, Ricardo A COL USARMY DHA DHSS \(USA\)](#); [Shivji, Shabbir CIV \(USA\)](#)
Cc: [Elliott, Robin](#)
Subject: DHA Request For Additional Information MC624081
Date: Thursday, January 14, 2021 3:04:00 PM

License No. 45-35423-01
Docket No. 03039046
Mail Control No. 624081
Licensee: Defense Health Agency

Colonel Reyes,

This is in reference to your letter dated December 14, 2020, requesting to amend NRC License No. 45-35423-01. In order to continue our review, we need the following additional information:

1. Item I.C of your letter states, in part, that “there is not a direct line of Command authority between the MTF and the laboratory” and “the laboratory is not an MTF but an area with limited use.” The additional address will be added to the list of authorized facilities; however, please confirm that DHA has authority at the laboratory to enforce NRC’s regulatory requirements under the DHA broad scope license. If this is not the case, that use will need to be covered under its own license.
2. Item I.D(2) of your letter requests to add Major Isaac A. Stephen as an ARSO for 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000 (Y90 microspheres). We can approve his authorization for everything except 35.1000 (Y90 microspheres) based upon his use with those materials under the Wright-Patterson AF Permit. However, the preceptor to add the 35.1000 authorization was signed by Major Steven Cho. Under the current credentials listed under Condition 12.D. of your NRC license, Major Cho does not have 35.1000 authorization and is therefore not qualified to sign as a preceptor. Please submit additional documentation to support your request to add Y90 for Major Stephen, such as completed vendor training or a revised 313A(RSO).
3. Item I.F. of your letter requests to add 35.1000 (RSL) authorization for Major Steven Cho. The current credentials for Major Cho listed under Condition 12.D. of your NRC license, does not have 35.1000 authorization. Therefore, in accordance with the requirements found in our licensing guidance, “Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes,” Revision 1, dated October 7, 2016, which can be found at the following link: <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>, please submit additional documentation that he has received the necessary training in the radiation safety, regulatory issues, and emergency procedures for RSL. This training requirement may be satisfied by completing training that is supervised by an individual (RSO or AU) that is authorized for RSL procedures.
4. Item 12(M) of your letter requests to add 35.1000 (RSL) authorization for Mr. Kevin Martilla. The current credentials for Mr. Martilla under Condition 12.D. of your NRC license, only has 35.1000 authorization for Yttrium-90 microspheres. Therefore in accordance with the requirements found in our licensing guidance, “Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph

Nodes", Revision 1, dated October 7, 2016,(see link above), please submit additional documentation that he has received the necessary training in the radiation safety, regulatory issues, and emergency procedures for RSL. This training requirement may be satisfied by completing training that is supervised by an individual (RSO or AU) that is authorized for RSL procedures.

5. Item I.D(5) requests to add Captain Houston T. Carlson as an ARSO for 35.100, 35.200, and 35.300 uses. Please note that the Form 313A (RSO) submitted requires additional information. Specifically, the box at the bottom of page 3 (under section 5.b.) should contain what materials he wishes to be authorized for, e.g. 35.100, 35.200, and 35.300. Additionally, under the second section to the preceptor attestation, at the bottom of page 5, the preceptor did not check 35.300 for the type of use being attested. Please submit a new Form 313A with this information. We also noted that you submitted training in 35.400 and 35.600 uses. Although you didn't request those authorizations, please keep in mind that you may add more authorizations than needed as ARSO's can be utilized anywhere under your license and not designated to one specific Command.
6. Item I.D(6) requests to add Staff Sergeant Steven L. Hayes as an ARSO for 35.100, 35.200, and 35.300 uses. Please note that the Form 313A (RSO) submitted had Box number 3 checked in Part I as a current authorized user or medical physicist. We were not able to verify that SSGT Hayes was an authorized user under the permit number you provided on the Form 313A. We did notice, however that Box number 5, "Structured Educational Program," was not checked but the data was included. Please confirm that you meant to check Box 5 and NOT Box 3. We were able to verify that the preceptor was the ARSO under that permit.

We will continue our review upon receipt of this information. Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email (preferred method during the pandemic); or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary

information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5102 or via electronic mail at shawn.seeley@nrc.gov.

Thank you for your cooperation.

Sincerely,

Shawn W. Seeley, Health Physicist
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Region I

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