From: Elliott, Robin
To: Reyes, Ricardo A COL USARMY DHA DHSS (USA); Shivji, Shabbir CIV (USA)
Subject: Request for Additional Information, License no. 45-35423-01, CN618057
Date: Thursday, March 12, 2020 9:36:00 AM

License No.: 45-35423-01
Docket No: 030-39046
Control No: 618057

Licensee Name: Defense Health Agency

This refers to your request to amend your license dated January 24, 2020 and addendum dated March 5, 2020. In order to continue our review of your request, the following additional information is needed:

1. Item 1. A. You have requested that the source activity of your HDR be increased to 12 Ci at the time of medical use. The NRC lists HDR models for which this increase is approved. https://www.nrc.gov/materials/miau/med-use-toolkit.html#dose (See ADAMS document no. ML19191A141) In order to evaluate your request, please confirm the model number and provide the serial number of your unit.
2. Item 1.C. requests that 18511 Heavy Metal Medics Street, Fort Bliss, TX 79918 be added to the license. This location was not on Amendment 82 for William Beaumont Army Medical Center as transferred to your license and was therefore not reviewed by NRC. Please confirm that your broad scope RSC reviewed the facility in accordance with the guidance provided by NUREG 1556, Vol. 9, Rev 3, including:

    - Facility diagrams. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
    - Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.
    - Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET).
    - Doors should be indicated, and specify which doors are access controlled (i.e., locked).
    - Shielding calculations for PET facilities, and in-patient rooms for 10 CFR 35.300. Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.
    - For PET, radiopharmaceutical, and sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.

If any therapy devices (e.g., high dose-rate remote after loader) will be used in these facilities, please submit the above information to the NRC for further review.

3. Item 1.H. requests that 10 CFR 35.400 and 10 CFR 35.600 (Iridium-192 HDR) be added to the current authorizations for Mr. Shabbir Shivji as an ARSO; however, no additional supporting documentation was submitted. The permit provided in Amendment 4 to support his current authorizations did not include 10 CFR 35.400 and 10 CFR 35.600 (Iridium-192 HDR). Please provide additional documentation to support this request.
4. Item 1.I requests that SIRspheres be added to the 10 CFR 35.1000 (microspheres) authorization for Mr. Fota. This is not needed since microspheres encompasses both Theraspheres and SIRspheres.
5. Item 1.J requests that Daniel Shaw be added as an ARSO for 10 CFR 35.600(Yttrium-90 microspheres). Please clarify if you are requesting both 10 CFR 35.600(Ir-192 HDR) and 10 CFR 35.1000(Y-90 microspheres) or simply 10 CFR 35.600 (Ir-192 HDR). If you are requesting 10 CFR 35.1000(Y-90 microspheres) please provide additional documentation to support this authorization.
6. Item II requests that COL Ricardo Reyes, Ph.D. be named as Radiation Safety Officer for the license and provides a Delegation of Authority Letter. Please clarify the following regarding the letter:
    - "You are granted "by direction" signature authority to sign such correspondence as may be required to perform your duties." Does this specifically include notifications, amendments, renewals, etc. for licensing matters?
7. Item III requests a line item be added to the license for materials authorized under 10 CFR 35.65. This is not required as 10 CFR 35.65 authorizes the use of these materials to any license issued under 10 CFR Part 35. Therefore, you are already authorized for these materials. However, you will need to assure that your permittees confirm that the material obtained for these purposes falls under the restrictions specified in 10 CFR 35.65. See below:

    35.65 Authorization for calibration, transmission, and reference sources.

    (a) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

    (1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations;

    (2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

    (3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);

    (4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCI) or 1000 times the quantities in appendix B of part 30 of this chapter; or

    (5) Technetium-99m in amounts as needed.

    (b) Byproduct material in sealed sources authorized by this provision shall not be:

    (1) Used for medical use as defined in § 35.2 except in accordance with the requirements in § 35.500; or

    (2) Combined (*i.e.,* bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph (a) or (b) of this section need not list these sources on a specific medical use license.

8. Item IV requests the listing of a line item for 500 mCi of Gd-153 sealed sources for imaging cameras. In order to add this line item, please provide the source description(s); manufacturer, model number and serial number for the sources to be listed, and the maximum activity permitted by the certificate of registration for each.
9. Item V requests that the leak test frequency for alpha emitting sealed sources be changed to six months. License Condition 16(B) allows for leak test frequencies longer than three months if it is designated as such in the certificate of registration. Frequencies longer than three months for alpha sources are not otherwise authorized. You may request a specific exemption as indicated in 10 CFR 35.19.
10. With regard to the March 5, 2020, addendum to the January 24, 2020 request:
    - A 313A (RSO) form was provided for Ramiro A. Cruz. Please confirm if the following is correct regarding the quoted dates on the form:
        i. 04 Jan 17-22 means January 17-22, 2004
        ii. May 17 means the month of May 2017
        iii. 06 Feb 18-15 means February 15-18, 2006
        iv. Mar 19 means the month of March 2019
    - Please indicate if you request Mr. William House to be authorized for 35.300 in addition to 35.100 and 35.200 as reflected on the Veterans Administration permit that was provided to support his addition.
10. Lastly, ARSO listings on licenses are based on authorizations rather than location. As a result, please confirm that the following individuals should be removed from the DHA license Condition 12:
    - TSgt Natalie Shimasaki-Alenepi
    - CDR Kristin S. Wehrung
    - MAJ Joshua Hubbell
    - LCDR John R. Pavlica
    - MAJ Timothy J. Smith

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; 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 request. Please feel free to contact me with any questions or concerns regarding this request.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Regards,

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