Torres, RobertoJ

From:	James Kay <jkay@guamradiology.com>
Sent:	Thursday, July 28, 2016 7:35 PM
To:	Torres, RobertoJ
Cc:	Nathaniel Berg
Subject:	[External_Sender] NRC request for additional information Amendment of Materials License Number: 56-27702-01
Attachments:	GMIC_ltr_to_NuclearMatlsLicensing_07292016.pdf

Dear Mr. Torres,

Here is the letter with the information you requested. If you are in need of any further information feel free to contact me at the address below.

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July 29, 2016

To: Robert J. Torres, M.S.
Nuclear Materials Licensing/Amendments Section
U.S. Nuclear Regulatory Commission, Region IV
1600 East Lamar Blvd
Arlington, TX 76011-4511

Subj: Amendment of Materials License Number: 56-27702-01

Dear Mr. Torres,

In response to your email dated July 28, 2016, here are the answers to your questions.

1. Ra-223 will be authorized as a separate line item in the license. What is the maximum possession limit, including waste, that you need authorized in the license for Ra-223?
    a. Since nothing radioactive can be shipped off of Guam, and the half-life is 11.4 days, I would request a 20 mCi limit just to ensure we do not exceed the limit while waiting for waste to decay. I know the average dose is around 100 uCi, but Guam tends to have a heavier population, so I would rather err on the side of caution than exceed our license limit.
2. What is the route of administration for Ra-223? Intravenous, intramuscular, oral, parenteral? I believe the route is intravenous but need confirmation from you.
    a. You are correct, we would be delivering the dose intravenously.
3. What is the form of Ra-223? Liquid, solid (pills), other? I believe the form is liquid but need confirmation from you.
    a. It would be delivered in liquid form.
4. Confirm that the Ra-223 that will be received in your facility will be in "unit dosages" already prepared by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j). State who the manufacturer(s) or preparer(s) of Ra-223 will be and I will determine if the they meet the 10 CFR 32.72 or 10 CFR 30.32(j)

criteria. The confirmation that I need from you is that you will receive "unit dosages" only of Ra-223 (i.e., you are not the manufacturer or preparer of Ra-223 unit dosages).

   a. We would be receiving only unit dosages, these would come directly from Bayer Pharmaceuticals Division; Bayer HealthCare Pharmaceuticals Inc.; BHP-BPH-US-US-NTAC-RTS, Radio Therapy Building B200, 2B2304; Whippany, NJ 07981, USA

5. If administering dosages of Ra-223 in other than unit dosages made by a manufacturer or prepares licensed under 10 CFR 32.72 or 10 CFR 30.32(j) [i.e., you are the preparer of Ra-223 unit dosages for administration to your patients], provided a statement that: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation" or state that this is not applicable.

   a. This is not applicable as we would be receiving unit dosages.

Thank you,

Nathaniel B. Berg, M.D.
Radiation Safety Officer

Cc: James M. Kay, CNMT (jkay@guamradiology.com) clinic administrator