



CONVERSATION RECORD

11/21/2013

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Timothy R. Quinton, R.Ph., President, Radiation Safety Officer & Owner		DATE OF CONTACT 11/21/2013	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS quinton@radiopharmacy.com		TELEPHONE NUMBER (812) 421-1002	

ORGANIZATION Radiopharmacy Incorporated	DOCKET NUMBER(S) 030-31910
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LICENSE NUMBER(S) 13-26246-01MD	CONTROL NUMBER(S) N/A
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SUBJECT
Your recent inquiry regarding requirements to add radium-223 dichloride (alpharadin/Xofigo) to your radioactive materials license

SUMMARY

We have reviewed Nuclear Regulatory Commission requirements for the licensing of radium-223 dichloride, for radiopharmacy use, including preparation and distribution. Additional information is needed from you, to complete your request to add radium-223 dichloride to your radiopharmacy radioactive materials license.

Direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

Submit requested information within 28 days of this record, referencing your NRC License No., 13-26246-01MD. Please FAX your response to my attention at (630) 515-1078. You may also scan your response and send to me via email, as a pdf file. Include a signed and dated cover letter with your response.

As discussed, we expect to receive your written response by close of business on or before December 17, 2013. If you are unable to respond by that date, please contact us and notify us when you may be able to respond..

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ACTION REQUIRED (IF ANY)

We have requested that the licensee provide additional information as follows:

- Radioactive material description, commitments, and purpose of use, as noted, for radium-223 dichloride
- Training program revisions related to use of radium-223 dichloride
- Dosage measurement, labeling, and shielding information, as noted, for radium-223 dichloride

NAME OF PERSON DOCUMENTING CONVERSATION
Sara A.B. Forster, Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532

SIGNATURE
Sara A.B. Forster 11/21/2013

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

T. Quinton

RADIOACTIVE MATERIAL TO BE AUTHORIZED:

1. List radionuclide (e.g., radium-223), maximum radium-223 activity to be possessed or used, and purpose of use. Describe all licensed material to be distributed, including the chemical and physical form. Please also explain your request for a 100 mCi possession limit for radium-223 dichloride, and confirm that this possession limit is needed.
2. Please confirm that, "Material to be used is radium-223 dichloride, manufactured for Bayer HealthCare Pharmaceuticals Inc."
3. Please confirm that, "No actinium-227 generators will be ordered, received, stored, and/or used, for the purpose of radium-223 radiopharmaceutical preparation."

PURPOSE OF USE:

4. Please confirm that, "For radium-223 radiopharmaceutical preparation, the purpose of use will be for the preparation, distribution, and redistribution of radium-223 dichloride."

TRAINING:

5. Please confirm that your training program will be, or has been, extended to ensure that the Radiation Safety Officer, Authorized Nuclear Pharmacists, occupationally exposed workers, ancillary personnel, and personnel involved in hazardous materials package preparation and transport are trained in the safe use, regulatory requirements, and the hazards associated with the use of radium-223 dichloride.

DOSAGE MEASUREMENT SYSTEMS, PROCEDURES, and CALIBRATION FACTOR VERIFICATION:

6. Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of radium-223 drugs, and to determine background readings.
7. Attach a copy of written procedures for the performance of dosage measurement, for radium-223 drugs, for each dose calibrator.
8. Calibration Factor Verification: Demonstrate the method used for any calibration factors used in determining radium-223 dosages by including the applicable item noted below (mark the response that is applicable):
 - a sample calculation for determining calibration factors for dose calibrators with ionization chambers is attached; or
 - a means for ensuring the accuracy of calibration factors supplied by the instrument manufacturer or other entity is attached.
9. Please indicate how you will acquire the appropriate NIST traceable source, necessary for dosage measurement system calibration.

RADIOACTIVE DRUG LABELING and SHIELDING for DISTRIBUTION:

10. Describe all-labels, indicating the colors to be used, that will accompany the radium-223 drug products, describe where each radium-223 drug label is placed (e.g., on the "transport radiation shield" or on the container used to hold the radioactive drug), and agree to affix the required labels to all "transport radiation shields" and to each container used to hold the radioactive drugs.
11. For each radium-223 dichloride drug to be distributed, provide the maximum radium-223 activity for each type of container (e.g., vial, syringe); a description of the type and thickness of the "transport radiation shield" provided for each type of container; and the maximum radiation level to be expected at the surface of each "transport radiation

Forster, Sara

From: Forster, Sara
Sent: Thursday, November 21, 2013 8:59 AM
To: 'quinton@radiopharmacy.com'
Subject: Additional information request for Radiopharmacy Incorporated, NRC Lic. No. 13-26246-01MD
Attachments: 02500.58____.13-26246-01MD telecon signed.pdf

Dear Mr. Quinton:

Please see attached for information needed to review a request for an authorization for radium-223 dichloride. My colleague Colleen Casey and I will call you at 2:00 pm this afternoon to discuss. We look forward to speaking with you then.

Sara A. B. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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