

Radiopharmacy, Inc.

Pharmaceuticals, Supplies and Equipment for Nuclear Medicine

March 7, 2014

Sara A.B. Forster, M.S.
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road
Lisle, IL 60532

Re: NRC License Number: 13-26246-01MD
Control Number: 580941

Dear Ms. Forster,

I am writing to resubmit my request that NRC License No. 13-26246-01MD be amended to include authorization to possess radium-223 (Ra-223) as directed in the Conversation Record (NRC FORM 699) from you dated November 11, 2013.

Attached are my responses to the "ACTIONS REQUIRED" listed in the above mentioned NRC Conversation Record.

If you need additional information or have any questions, please call me. Thanks for your help.



Tim Quinton, RPh
President, Radiation Safety Officer & Owner

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Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road
Lisle, IL 60532

Re: NRC License No. 13-26246-01MD

Responses to ACTION REQUIRED regarding requirements to add radium-223 to radioactive materials license.

Radionuclide: radium-223

Maximum activity to be possessed or used: 5 millicuries

Purpose of use: For the preparation, distribution, and redistribution of radium-223 dichloride

Chemical and/or physical form: Dichloride/liquid

Material to be used is US FDA-approved drug, radium-223 dichloride, currently manufactured exclusively for Bayer Healthcare Pharmaceuticals Inc. No actinium-227 generators will be ordered, received, stored, and/or used, for the purpose of radium-223 radiopharmaceutical preparation.

Radiopharmacy, Inc.'s training program will be 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 transportation are trained in the safe use, regulatory requirements, and the hazards associated with the use of radium-223 dichloride. All other existing radiation safety procedures will incorporate consideration of the potential presence of radium-223.

Radiopharmacy will utilize the manufacturer's recommended procedure for assaying doses. A copy of Radiopharmacy's written procedure for performance of dosage measurement for radium-223 drugs is attached. We will utilize the manufacturer product vial's NIST traceable assay information for dosage measurement system calibration prior to dispensing all dosages.

Labels will include all information required by all regulatory agencies (i.e., NRC, Boards of Pharmacy, FDA, DOT). Labels will be affixed to all "transport radiation shields" and each container (e.g., syringe) used to hold the radioactive drug. An example of the drug labeling is attached.

each container (e.g., syringe) used to hold the radioactive drug. An example of the drug labeling is attached.

The maximum radium-223 activity dispensed in any single container (syringe or vial) is 250 uCi. Transport radiation shields will be same as those used by Radiopharmacy when transporting other routine radiopharmaceutical products. The minimum lead thickness of these transport radiation shields is 0.25 inches, and the maximum radiation level expected at the surface of each drug to be distributed is less than 5 mR/hr.

If you need additional information or have any questions, please call me. Thanks for your help.

A handwritten signature in black ink, appearing to read "Tim Quinton". The signature is fluid and cursive, with a horizontal line extending from the end of the name.

Tim Quinton, RPh
President, Radiation Safety Officer & Owner

RX#526898
Radium (Ra) 223 Dichloride
Deaconess Hospital
100 uCi 17:00
TEST PATIENT

03/07/2014 17:00
Box: 15:00 - 1

*Transparent
 Radiation
 Shield
 Labels*

RX#526898
Radium (Ra) 223 Dichloride
100 uCi
Cal Date: 03/07/2014
Cal Time: 17:00
TEST PATIENT

*Yellow
 Background*

*Syringe
 Vial
 Label*

Radiopharmacy, Inc 812-421-1002
 1400 E. Virginia
 Evanoville, IN 47711
RX#526898 License: 13-26246-01MD
Account Name: Deaconess Hospital
 600 Mary Street
 Evanoville, IN 47747
Delivery D/T: 03/07/2014 15:00 Container: 1
Patient: TEST PATIENT
Product: Radium (Ra) 223 Dichloride
Procedure: Bone Metastases Treatment
Physician: Ryan Meyer
Ordered Amount: 100 uCi Quantity: 1 Adm. Amt: uCi
Cal Date/Time: 03/07/2014 17:00
Actual Amount: 100.00 uCi Quantity: 1 Volume: 3.70 ml
Exp Date/Time: 03/14/2014 17:00
Filled By: Nicole Spurling
Lot #(s): DUMMY LOT 3.704
 107ES1
CAUTION: RX ONLY
 WARNING: Federal or State Law prohibits the transfer of this prescription to any person other than the person for whom it was prescribed



Procedure for Measurement of Radium-223 Drugs

Radiopharmacy utilizes a combination of measurements and calculations to determine the dosage of radium-223 drugs

1. Record the activity, calibration date/time, and volume of radium-223 product vial

Activity: _____ uCi

Calibration Date/Time: _____

Volume: _____ ml

2. Calculate the activity present currently from manufacturer calibration information and appropriate radioactive decay factor for radium-223

Current Activity: _____ uCi

3. Adjust dose calibrator setting (calibration setting) so that the activity displayed equals the decay corrected activity calculated in Step 2. in the manufacturer supplied product vial.

Calibration Setting: _____

Current Activity: _____ uCi

4. Calculate the volume to be withdrawn from radium-223 vial based on current activity concentration and desired patient dosage.

Current Activity Concentration (A) : _____ uCi/ml

Patient Dosage (B): _____ uCi

Dosage Volume (B/A): _____ ml

5. Withdraw dosage volume from product vial
6. Add quantity of sterile 0.9% NaCl (Saline) solution equal to the patient dosage volume to the product vial in order to bring the volume in vial back to its original volume.

7. Assay the residual activity in the product vial in the dose calibrator.

Activity: _____ **uCi**

8. Subtract activity from Step 7. from original activity measured in Step 3. to determine patient dosage activity in unit dose syringe withdrawn from product vial.

Patient Dosage Activity: _____ **uCi**

Forster, Sara

From: Tim Quinton <quinton@radiopharmacy.com>
Sent: Friday, March 07, 2014 1:14 PM
To: Forster, Sara
Subject: License # 13-26246-01MD Amendment
Attachments: Cover Letter - resubmission.pdf; Ra-223 resubmission.pdf

Sara,
Sorry for the delay getting this back to you. But, attached is my reply to your last correspondence regarding our request that Rs-223 be added to our RAM license.
Please let me know if you need anything else.
Thanks,

Tim Quinton, PharmD, MS, BCNP, FAPhA
President/Owner
812.421.1002

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