CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

Steven L. Beshear
Governor

Division of Public Health Protection & Safety
Radiation Health Branch
275 East Main St. Mailstop HS1C-A
Frankfort, KY 40621
502-564-3700 Phone
502-564-1492 Fax
http://chfs.ky.gov/dph/radiation.htm

Audrey Tayse Haynes
Secretary

Adding the Authorized Use of Radium 223 Dichloride to a Specific License

June 19, 2013

Licensees will submit an amendment request to the Radiation Health Branch along with a $75.00 check made payable to the Kentucky State Treasurer to add the authorized use of Radium 223-Dichloride, under 902 KAR 100:072, Section 33. Use of Unsealed Radioactive Material for Which a Written Directive is Required.(http://www.lrc.state.ky.us/kar/902/100/072.htm) The names of the individuals to be added as authorized users for Radium 223 and supporting documentation identified below:

1. Individuals added as authorized users for Radium 223-Dichloride must be current authorized users for 902 KAR 100:072, Section 70.Training for the Use of Unsealed Radioactive Material for Which a Written Directive is Required and/or Section 73. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive. The individual requesting to be added as an authorized user would need to supply a copy of an NRC, AS or KY RAM license that is less than seven (7) years old where they are listed for this authorized use or a completed RPS-8 AUT – Therapy Unsealed preceptor form on the RHB website at the following link http://www.chfs.ky.gov/dph/radioactive.htm.

2. A copy of the Written Directive that will be used for Radium 223-Dichloride that includes all regulatory requirements identified in 902 KAR 100:072, Section 14. Procedures for Administrations Requiring a Written Directive.

3. The written policy and procedure for administration of the Radium 223-Dichloride to ensure it provides “high confidence” the administration is in accordance with the written directive (WD). This should include how the dose administered will be determined. Please see 902 KAR 100:072, Section 14. Procedures for Administrations Requiring a Written Directive.

4. Training and information provided to authorized users and staff members for identification and report of a medical event as identified in 902 KAR 100:072, Section 15. Report and Notification of Medical Events related to the use of Radium 223-Dichloride.

5. The commitment to perform annual calibration on their dose calibrator and to assay the dose prior to and post administration. This information is identified in the FDA, Full Prescribing Information approved by the FDA and the use of the radiopharmaceutical Xofigo, located under 2 Dosage and Administration, 2.1 Recommended Dosage. This is a regulatory requirement based on 902 KAR 100:072, Section 79. Food and Drug Administration (FDA), Other Federal and State Requirements. Nothing in this administrative regulation

relieves the license from complying with applicable FDA, other federal and state requirements governing radioactive drugs of devices. (31 Ky. R 656, Am. 1163, eff. 1-4-2005; eff. 1-4-2005, 37 Ky.R 1837; 2627; eff. 6-3-11.) Based on the FDA FULL PRESCRIBING INFORMATION, under 2 DOSAGE AND ADMINISTRATION, 2.1 Recommended Dosage, identifies the type of NIST traceable dose and requirements related to calibration intervals. ***THE FDA DOES NOT INSPECT RAM LICENSES. THIS WOULD BE INSPECT ABLE BY THE RHB AND VIOLATIONS RELATED TO THIS WOULD BE REPORTABLE TO THE FDA BY THE RHB.***

6. Written radiation safety training information for all staff including the authorized user, technologist, nursing and ancillary staff who will be involved or could be exposed to the Radium 223-Dichloride.

7. Licensees are not to manipulate doses unless the NRC Notice FSME-13-002 for the licensing decision on Radium-223 Dichloride, issued on January 10, 2013 and the Full Prescribing Information approved by the FDA and provided for the use of Xofigo/Radium-223 approve manipulation by the licensee.

8. Information on how the licensee will handle the disposal and/or decay in storage of Radium-223. This includes all IV and related tubing for decay in storage.

9. Radiation Safety instructions given to the patient and/or their caregiver at the time they are released after each therapeutic treatment. This is not related to regulation identified in 902 KAR 100:072, Section 27. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material. Please review the FDA, Full Prescribing Information for specifics. Xofigo has included a "patient release card" but the licensee must also provide the RHB with Radiation Safety instructions provided to the patient. All of the documents provided by Xofigo include a copy of the FDA, Full Prescribing Information. Under 2.3, Instructions for Use/Handling, *Radiation Protection,* For patient care, there are comments that should also be provided to the patient that address radiation protection. These comments are also in 17, Patient Counseling Information. ***THE FDA DOES NOT INSPECT RAM LICENSES. THIS WOULD BE INSPECT ABLE BY THE RHB AND VIOLATIONS RELATED TO THIS WOULD BE REPORTABLE TO THE FDA BY THE RHB.***

The NRC Notice FSME-13-002 for the licensing decision on Radium-223 Dichloride, issued on January 10, 2013 does not contain many of the requirements identified in Full Prescribing Information approved by the FDA and provided for the use of Xofigo/Radium-223. The licensee is responsible for following regulatory requirements and Full Prescribing Information approved by the FDA, related to the use of Radium 223-Dichloride. The licensee is responsible for adhering to both regulatory requirements and FDA requirements, and adhering to the stricter requirement.

Documents for review on the Use of Radium-223 Dichloride:

- Radium-223 Dichloride: Bayer Responses to NRC Questions, dated November 8, 2012 http://pbadupws.nrc.gov/docs/ML1232/ML12320A450.pdf

- Full Prescribing Information approved by the FDA, related to the use of Radium 223-Dichloride http://pbadupws.nrc.gov/docs/ML1232/ML12320A450.pdf

- NRC Notice FSME-13-002 for the licensing decision on Radium-223 Dichloride, issued on January 10, 2013 http://pbadupws.nrc.gov/docs/ML1234/ML12341A253.pdf

- Xofigo (radium Ra 223 dichloride) Injection, for intravenous use FULL PRESCRIBING INFORMATION http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203971lbl.pdf