Illinois Emergency Management Agency
Guidance for Applicants Requesting Xofigo
(radium Ra-223 dichloride)

The U.S. Food and Drug Administration approved Xofigo (radium Ra-223 dichloride) to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs. It is intended for men whose cancer has spread after receiving medical or surgical therapy to lower testosterone.

Ra-223 Xofigo will be authorized as a 32 Ill. Adm. Code 335.5010 parenteral radiopharmaceutical requiring a written directive, and it must be administered under the supervision of an appropriately trained and authorized 5010 physician as detailed in 32 Ill. Adm. Code 335.9050. Alternately, authorized users can be trained in accordance with 32 Ill. Adm. Code 335.9080; however, their authorization will be limited to the use of parenteral radiopharmaceuticals only.

No amendments will be required to limited scope licenses that are authorized for 32 Ill. Adm. Code 335.5010. All other requirements in 32 Ill. Adm. Code 335 must be met. Broadscope licensees should verify that their broad authorization includes atomic number 88 for radium. Authorized user approvals should be evaluated in accordance with 32 Ill. Adm. Code 335.9050 or 9080.

Patients administered this product will meet the patient release criteria in 32. Ill. Adm. Code 335.2110. In addition, dose calculations indicate that doses to any other individual is much less than the limits requiring additional instruction to limit public doses. Patient counseling and universal precautions as noted in the package insert are recommended.

Ra-223 Xofigo is supplied to medical users as unit doses. The unit dose amount is 1.49 microCi/kg of body weight or 55 kBq/kg body weight.

Treatment regimens may run a total of a dose every four weeks for six cycles. Due to the half-life consideration, a slightly higher quantity is shipped to account for decay (Ra-223 has an 11 day half-life). Studies performed with pharmacy dose calibrators (CRC15 and CRC25) show that they can readily detect as low as 1% of this initial amount (thus being able to assure administration of the full amount by re-assaying a post injection syringe.) A reference dose of Ra-223 and instructions will be provided for pharmacies to determine the best settings for their own equipment. An appropriate radioassay system (e.g., a dose calibrator) for measurement of the Ra-223 activity prior to its administration or the residual activity following its administration is therefore recommended for the therapeutic use of 223RaCl2. Licensees will be able to use the actual dose to obtain the best calibrator settings. Additional geometrical testing will not be necessary

Tests done to determine if radiation survey meters can detect any associated Ra-223 contamination have been performed and pancake probes work very well for this purpose (approx. 20% eff and 288 dpm MDA) as do well counters (approx. 70% eff and 100 dpm MDA).

Tests to see if any radon daughters emanate from the vial were also performed with negative results. Any Ra-223 material not incorporated (~20%), is essentially released via the digestive tract in a week (~75%). Universal precautions are the key here as with any other radiopharmaceutical to prevent contamination of equipment, surfaces and personnel.

From a medical event perspective, the organs with highest absorbed radiation doses were bone (osteogenic cells), red marrow, upper large intestine wall, and lower large intestine wall. After intravenous injection, radium-223 is rapidly cleared from the blood and is distributed primarily into bone or is excreted into intestine. No significant uptake was seen in other organs such as heart, liver, kidneys, urinary bladder, and spleen at 4 hours post-injection. Further information on biodistribution and absorbed doses can be found in the package insert.

If you have questions about your license or other regulatory concerns regarding the use of Xofigo (radium Ra-223 dichloride), please contact Mary Burkhart at (217) 785-9934.