

STATE OF WISCONSIN INFORMATION NOTICE 2013-01

TO: Department of Health Services
Radioactive Material Licensees authorized for medical use

FROM: Department of Health Services, Radioactive Materials Program

DATE: May 21, 2013

SUBJECT: FDA Approval of Ra-223 dichloride (Xofigo®)

PURPOSE

The Wisconsin Department of Health Services (DHS) is issuing this information notice to inform licensees that DHS is licensing radium-223 dichloride ($^{223}\text{RaCl}_2$) under DHS 157.64(1), unsealed radioactive material which requires a written directive.

DESCRIPTION OF CIRCUMSTANCES

The Food and Drug Administration has recently approved the use of $^{223}\text{RaCl}_2$ for the treatment of skeletal metastases in late-stage castration-resistant prostate cancer. The Nuclear Regulatory Commission has recommended that $^{223}\text{RaCl}_2$ be licensed under 10 CFR 35, Subpart E “Unsealed Byproduct Material—Written Directive Required.”

DISCUSSION

Based on available information, DHS agrees with the Nuclear Regulatory Commission recommendation and determined that licensing under DHS 157.64(1) is appropriate because the medical use of $^{223}\text{RaCl}_2$ is similar to other commonly used beta and photon-emitting therapeutic radiopharmaceuticals. DHS has also determined that physicians who are approved for the use of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV under DHS 157.64(4), “Training for Use of Unsealed Byproduct Material for which a Written Directive is Required,” or DHS 157.64(7), “Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive,” are authorized for the medical use of $^{223}\text{RaCl}_2$. Therefore, licensees do not need to amend their license to use $^{223}\text{RaCl}_2$ if the license already permits use of “any radioactive material authorized by DHS 157.64(1).”

DHS expects licensees to follow the manufacturer’s instructions regarding the appropriate radiation safety precautions for handling this radiopharmaceutical.

QUESTIONS OR ADDITIONAL INFORMATION

This Information Notice requires no specific action or written response. If you have any questions about the information in this notice, please contact Megan Shober at (608) 287-4422 or by email at Megan.Shober@wi.gov, or Emily Eggers at (608) 266-7384 or by email at Emily.Eggers@wi.gov.