

May 22, 2013

Dear Licensee:

The purpose of this notice is to inform licensees that the U.S. Food and Drug Administration (FDA) has approved the use of Xofigo (Radium-223 dichloride) for the treatment of castration-resistant prostate cancer with bone metastases.

Licensing for the radiopharmaceutical will remain under 10 CFR Part 35, Subpart E. In addition, under current regulations, 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 10 CFR 35.390, "Training for use of Unsealed Byproduct Material for which a Written Directive is Required," or 10 CFR 35.396, "Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive," can be authorized for the medical use of Radium-223 dichloride. Any licensee/applicant requesting to use this drug will be required to submit all information required by 10 CFR 35.12 (b) through (d) and receive written approval from the Department.

In addition, the following information will need to be provided:

1. A commitment to follow the procedure for handling the radiopharmaceutical per drug manufacturer's protocol.
2. Names of the proposed authorized user(s) and documentation on their training and experience.

As discussed above, physicians authorized to use therapeutic radiopharmaceuticals under 10 CFR 35.390 or 35.396 already have the requisite education, training, and experience to safely and effectively use Radium-223 dichloride.

If you have any questions regarding this correspondence, please contact the Radioactive Materials Program at 609-984-5462.