IOWA DEPARTMENT OF PUBLIC HEALTH
BUREAU OF RADIOLOGICAL HEALTH
LUCAS STATE OFFICE BUILDING
DES MOINES, IOWA 50319

March 2013

IDPH INFORMATION NOTICE 2013-03 Notice of licensing decision on the use of Radium-223 dichloride ($^{223}RaCl_2$)

ADDRESSEES

All material licensees that are authorized to perform therapeutic procedures using radiopharmaceuticals

PURPOSE

The IDPH is issuing this information notice (IN) to alert addressees to the requirements for the medical use of Radium-223 dichloride ($^{223}RaCl_2$) under Iowa Administrative Code (IAC) 641-41.2(37).

DESCRIPTION OF CIRCUMSTANCES

Recently, the Nuclear Regulatory Commission (NRC) issued a licensing decision on the medical use of $^{223}RaCl_2$ under 10 Code of Federal Regulations (CFR) Part 35 Subpart E, "Unsealed Byproduct Material – Written Directive Required".

DISCUSSION

$^{223}RaCl_2$ is currently an investigational radiopharmaceutical undergoing clinical trials in the United States. It is not yet approved by the U.S. Food and Drug Administration (FDA). The intended application for $^{223}RaCl_2$ is for the treatment of skeletal metastases in advanced, castration-resistant prostate cancer.

The NRC has reviewed the radiation safety aspects of the medical use of $^{223}RaCl_2$ to determine if the radiopharmaceutical should be licensed under 10 CFR Part 35, Subpart E, "Unsealed Byproduct Material – Written Directive Required" or 10 CFR Part 35 Subpart K, "Other Medical Uses of Byproduct Material or Radiation From Byproduct Material". The Advisory Committee on the Medical Uses of Isotopes (ACMUI) evaluated the medical use of $^{223}RaCl_2$ and submitted a report recommending regulation under 10 CFR Part 35, Subpart E, "Unsealed Byproduct Material – Written Directive Required".

Based on available information, the NRC agreed with the ACMUI recommendation and determined that licensing under 10 CFR Part 35, Subpart E, "Unsealed Byproduct Material – Written Directive Required" is appropriate because the medical use of $^{223}RaCl_2$ is similar to other commonly used beta and photon-emitting therapeutic radiopharmaceuticals. The NRC has also determined that 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 $^{223}RaCl_2$.

IDPH is notifying all licensees that are authorized to perform therapeutic procedures using radiopharmaceuticals that IDPH concurs with the determination of the NRC and the recommendation of the ACMUI. Licensees authorized in accordance with IAC 641-41.2(37), "Use of unsealed by-product material for which a written directive is required" and Authorized Users trained in accordance with IAC 641-41.2(69), "Training for use of unsealed by-product material for which a written directive is required" who are listed on the specific license are authorized for the medical use of $^{223}RaCl_2$.

If the IDPH becomes aware of future developments related to the production, distribution, or medical use of $^{223}RaCl_2$ that may negatively impact radiation safety, IDPH will consider revisiting this licensing decision for any additional actions.

CONTACT

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact this office.

Melanie Rasmusson, Chief
Bureau of Radiological Health
515-281-3478
melanie.rasmusson@idph.iowa.gov