



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

January 17, 2013

Docket No. 03001303  
Control No. 577625

License No. 07-12153-02

Patrick Grusenmeyer, D.Sc.  
Senior Vice President, Cancer and Imaging Services  
Christiana Care Health Services  
Room 1127 - MAP 2  
4755 Ogletown-Stanton Road  
Newark, DE 19718

SUBJECT: CHRISTIANA CARE HEALTH SERVICES, ACCEPTANCE OF NOTIFICATION,  
AMENDMENT NOT NEEDED, CONTROL NO. 577625

Dear Mr. Grusenmeyer:

In your letter dated May 16, 2012, you requested addition of Radium-223 dichloride ( $^{223}\text{RaCl}_2$ ) to your license to be used under the supervision of Drs. Manzone, Dam, and Grady. Please note that on January 10, 2013, the Nuclear Regulatory Commission issued a letter documenting the review of this issue (ML12349A275) and indicated the following:

1. Licensing under Title 10 of the Code of Federal Regulations (10CFR) Part 35, Subpart E "Unsealed Byproduct Material – Written Directive Required" is appropriate.
2. 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  $^{223}\text{RaCl}_2$ .
3. The current methods of distribution (unit dosages) preclude the need for end users to manipulate  $^{223}\text{RaCl}_2$ .

In addition, we understand that the dosage is prepared for use in research in accordance with an Investigational new drug (IND) protocol accepted by FDA as required by 10 CFR 35.300.

Since your license already authorizes full use under 10 CFR 35.300 and authorized users for these uses, an amendment is not needed. Your letter is accepted as notification that you plan to conduct this activity. No further correspondence on this subject is necessary.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture

P. Grusenmeyer

2

Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you for your cooperation.

Sincerely,

***Original signed by Penny Lanzisera***

Penny Lanzisera  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

cc:  
Joseph F. Solge, Jr., Radiation Safety Officer

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**SUNSI Review Complete: PLanzisera**

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