



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

July 18, 2013

Docket No. 03001267
Control No. 581170

License No. 06-06941-01

Balachandran Kodery
Radiation Safety Officer
Norwalk Hospital
24 Stevens Street
Norwalk, CT 06856

SUBJECT: NORWALK HOSPITAL, ACCEPTANCE OF NOTIFICATION, AMENDMENT NOT NEEDED, CONTROL NO. 581170

Dear Mr. Kodery:

In your letter dated May 23, 2013, you requested addition of Radium-223 dichloride ($^{223}\text{RaCl}_2$) to your license to be used under the supervision of Dr. Strauss. 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 Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We

B. Kodery

2

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.

Your cooperation is appreciated.

Sincerely,

Original signed by Penny Lanzisera

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

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