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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

JUL 23 2013

Mack L. Richard, M.S..
Radiation Safety Officer
IUPUI/Indiana University Medical Center
541 Clinical Drive
Indianapolis, IN 46202

Dear Mr. Richard:

Enclosed is Amendment No. 96 to your NRC Material License No. 13-02752-03 in accordance with your request. **We have also added Condition 14.I., in accordance with current licensing policy.** Changes made to your license are printed in **bold font**.

Please note that on January 10, 2013, the U.S. Nuclear Regulatory Commission issued a letter to Bayer HealthCare Pharmaceuticals, Inc. ("Bayer letter"; ML 12349A275). The Bayer letter confirmed that the use of $^{223}\text{RaCl}_2$, as requested and described in your letter, is authorized for entities authorized for 10 CFR 35.300 radioactive materials use, as described in Title 10 of the *Code of Federal Regulations* (CFR), Subpart E, "Unsealed Byproduct Material – Written Directive Required". Since the previous amendment to the above referenced license limits your medical use authorization to byproduct material with atomic numbers 1-83, we have added a $^{223}\text{RaCl}_2$ authorization with this amendment.

Also note that the Bayer letter indicated that all Authorized Users (AUs) currently 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,' are authorized for the medical use of $^{223}\text{RaCl}_2$.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

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M. Richard, M.S.

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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 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.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Sara A.B. Forster, M.S.
Health Physicist
Materials Licensing Branch

License No. 13-02752-03
Docket No. 030-01609

Enclosure: Amendment No. 96