

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

JAN 04 2012



Yun Wang, Ph.D.
Radiation Safety Officer
Central Indiana Cancer Centers
1346 East County Line Road
Indianapolis, IN 46227

Dear Dr. Wang:

Enclosed is Amendment No. 19 to your NRC Material License No. 13-32241-01 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

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. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

This amendment incorporates most, but not all, of the changes mentioned in your letter received October 31, 2011.

We were unable to approve Paul Des Rosiers, M.D. as an authorized user for the use of materials in 10 CFR 35.300 because the information in your letter received on October 31, 2011, was insufficient to complete our review.

If you wish to pursue this request, please provide a written response, currently dated and signed by a senior management official, to the information requested below and attached. Please address your response to my attention at the above address and reference it as "additional information to control number 576302" to facilitate proper handling in our office.

Dr. Des Rosiers was not approved as an authorized user for the use of materials in 10 CFR 35.300 because there were several discrepancies identified in the information supporting the request that were inconsistent and incomplete, with respect to demonstrating compliance with 10 CFR 35.390 and 10 CFR 35.396.

Your letter states that you wish to add Dr. Des Rosiers "as the Authorized user for the 10.CFR 35.300 for using Quadramet and Zevalin."

Quadramet and Zevalin are materials used under either 10 CFR 35.390 or 10 CFR 35.396 only.

However, the NRC Form 313AUT shows that Dr. Des Rosiers is requesting authorization

~~Official Use Only - Security-Related Information~~

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

Y. Wang

for all of 10 CFR 35.300, therefore necessitating compliance with all of 10 CFR 35.390.

Further, certain sections of the Form 313AUT are incomplete, inconsistent (referring to subparts of 10 CFR 35.390, such as 35.392, 35.394 and 35.396, which is incorrect and confusing) and are inadequately supported by the specialty board certification provided.

Please see the "marked up" copy of these forms for specific notes on what appears to be incomplete and inconsistent. Certain sections were also left blank, which, depending on the authorization pathway you choose to take, may not be appropriate so those sections may need to be completed.

Please refrain from using shortcuts we do not understand, such as "IU residency" as a location of training. This is very non-specific. Please identify a location by means of its institutional name and full address.

Since it appears that multiple, conflicting pathways to authorization were attempted, this contributed greatly to the confusion surrounding your request and the quality of the forms submitted.

Please determine what Dr. Des Rosiers wants to become authorized for specifically and identify that to us.

Then, select one pathway to demonstrate his training and experience qualifications in support of the proposed authorization and provide complete, accurate evidence via a revised set of preceptor forms that are currently dated and appropriately signed.

Please also see the list of specialty board certifications that we can accept at:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html> excerpted as follows:

"§35.390 Training for use of unsealed byproduct material for which a written directive is required **American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians before and after these dates issued an ABNM certification with the word "United States" appearing under the certification number. ***

American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal. *

American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty. *

*Diplomates of this specialty board also satisfy the training and experience requirements in 10 CFR 35.392 and 35.394. "

T. Wang

According to our website, we cannot accept Dr. Des Rosiers' specialty board certification for 10 CFR 35.390 because it does not say "AU eligible" above the seal. There is no specialty board certification accepted just for 10 CFR 35.396.

In addition, the hours of didactic training required for 10 CFR 35.390 compliance is 200. Dr. Des Rosiers presented only 160 hours of training, all of which was obtained more than seven years preceding the current date of application, which does not comply with 10 CFR 35.59, "Recentness of training."

Please refer to the above regulatory requirements, the attached "marked-up" copy of Dr. Des Rosiers' forms, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Revision 2, for assistance in preparing your response. NRC's regulations and the Guidance document referenced, NUREG 1556, Vol. 9, Rev. 2, are available on our website through <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.790, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

If you have questions concerning this issue please contact me at (630) 829-9841 or (800) 829-9500, ext. 9841. My fax number is (630) 515-1078.

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 Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

T. Wang

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.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 13-32241-01
Docket No. 030-35383

Enclosure:

Amendment No. 19