



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

OCT 17 2011

Edward E. Wroblewski, M.A.
Radiation Safety Officer
St. Vincent Hospital &
Health Care Center
2001 West 86th Street
Indianapolis, IN 46240-0970

Dear Mr. Wroblewski:

Enclosed is Amendment No. 130 to your NRC Material License No. 13-00133-02 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. If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025.

In reviewing the letter dated July 15, 2011, we noted that it was minimally adequate in supporting Dr. Martinez' application to become an authorized user for materials in 10 CFR 35.300 and yttrium-90, permitted by 10 CFR 35.1000, in the SIR-spheres therapy delivery system. This is because the letter signed by the RSO for the University of Illinois at Chicago was minimally adequate in stating the information requested in NUREG 1556, Vol. 9, Appendix D, section V. A copy of Appendix D was attached to our letter to you dated June 22, 2011, which also referred you to it for assistance in preparing your response.

For future reference, please obtain a letter signed by an appropriate senior management official, or RSO or RSC Chairperson, that specifically states the name of the physician who provided preceptor training, which timeframes s/he was an authorized user, which modalities s/he was an authorized user for. Whenever broad scope licenses, Agreement State licenses or Master Material licenses are used for references, this guidance should be followed closely to ensure that complete and accurate information is submitted to us.

Please do not submit copies of minutes from the licensee's RSC meetings or other documents from the Agreement State licensee or extraneous documentation that we must protect, per 10 CFR 2.390.

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing future requests.

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

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

E. Wroblewski

Please note that consulting these references, in particular Appendix D, all of it and especially section V. for Agreement state licenses and broad scope licenses, and understanding them and applying them to future requests should be very helpful in preparing an appropriate response.

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."

Please note that I adjusted the locations of use specified for use of the SIR-spheres in accordance the representations made in your July 15, 2011, letter.

In addition, your letter dated July 15, 2011, included a previously missing training commitment from the 10 CFR 35.1000 guidance for yttrium-90 SIR-spheres on our website that is to be used when applying for this modality.

Therefore, I deleted Condition No. 19 , as it appeared on Amendment No. 129, because your commitment is "tied-down" in new Condition No. 19 in the July 15, 2011, letter, which captures this training commitment.

I also corrected and completed Condition No. 15.G.

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).

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.

E. Wroblewski

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. 21-01333-02
Docket No. 030-01579

Enclosure:

Amendment No. 130