



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352
AUG 01 2010

Randall J. Phillips, M.D.
Radiation Safety Officer
QHG of Indiana
7950 W. Jefferson Boulevard
Fort Wayne, IN 46804-1677

Dear Dr. Phillips:

Enclosed is Amendment No. 66 to your NRC Material License No. 13-01535-01 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.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078.

Please note that I was unable to approve your request to add SIRTex Model Sirspheres to your license at this time because your letter dated April 27, 2010, did not include a possession limit for this material, as required, and no authorized physician users were proposed to use this material.

Please provide this information in a written response that is currently dated and signed by a senior management official, addressed to my attention and reference it as "additional information to control number 319034," to facilitate proper handling.

Please also include your fax number, as a check of our records indicates that we do not have this information on file for you. Upon receipt of your response, we will continue our review.

Please note that I was also unable to approve Ryan Buss, M.D. as an authorized user (AU) for materials in 10 CFR 35.100, 35.200 and 35.300, limited to iodine-131 only in quantities greater than and less than 33 millicuries at this time because the information in your letter dated May 13, 2010, was insufficient to complete my review.

If you wish to pursue this request, please submit the information requested below in accordance with the guidance given above.

Dr. Buss was not approved as an AU because we were unable to verify the qualifications of his preceptor, Dr. James Ball, because Dr. Ball references the license, under which training of Dr. Buss took place, as Wake Forest University Baptist Medical Center ("WFUBMC") in North Carolina.

R. Phillips

This is an Agreement State license (that we do not have access to) that could also be a broad scope license, i.e., it does not name AU's on its license document directly; rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.

Please submit a copy of the Agreement State License for WFUBMC, and, if appropriate, please also submit a letter currently signed and dated by the Chair of the Radiation Safety Committee stating which modalities Dr. James Ball was authorized for under the license and which timeframes he held said authorization.

Please do NOT submit copies of minutes from the licensee's RSC meetings or other documents from the Agreement State licensee, especially patient records, 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 your response.

If Forms 313a will be used in support of your response, please use the newly revised Forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

In addition, if you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, 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."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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>

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.

R. Phillips

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. 13-01535-01

Docket No. 030-01594

Enclosure:

Amendment No. 66