



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD STE 210  
LISLE, ILLINOIS 60532-4352  
DEC 05 2007

Sun-Shing Steven Leung, Ph.D.  
Radiation Safety Officer  
Elkhart General Hospital  
P.O. Box 1329  
Elkhart, IN 46515-1111

Dear Dr. Leung:

Enclosed is Amendment No. 40 to your NRC Material License No. 13-18879-01 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 you have any questions concerning this amendment, please contact me at either (800) 522-3025 or (630) 829-9841.

**Please note that I did not authorize Dr. Griffin for the use of materials in 10 CFR 35.500, as requested in your letter dated October 25, 2007, because your license does not authorize the possession or use of these materials and the request appeared to be a typo. I also added the vendor's name for your HDR sources in Subitem No. 7.F., which appeared to be missing.**

**At this time I was unable to approve Dr. Christine Marsch as an Authorized User for the use of materials in 10 CFR 35.300, limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries because the information in your letter dated September 6, 2007, was insufficient to complete my review.**

**If you wish to pursue this matter, please submit a written response to the information requested below, addressed to my attention as "additional information to control number 316512." We will then continue our review.**

**Dr. Marsch was not approved as an Authorized User for the use of materials in 10 CFR 35.300, limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries because the training and experience information submitted in support of her application did not appear to meet the requirements in 10 CFR 35.392.**

**Specific information lacking included the identity of the medical license, including name and license number (and, if an Agreement State license, a copy of the license), where Dr. Marsch obtained her training and experience in this modality; and the name of her supervising physician or preceptor and sufficient information permitting us to verify that her supervising physician or preceptor was qualified to oversee her training and experience at the times when she obtained the training and experience.**

**The document submitted as an attestation for Dr. Marsch appears to have been prospectively prepared, before she actually completed her training and experience, which is documentation that we do not accept.**

**Please be reminded of the requirements in 10 CFR 30.9, which states, in part, that “(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 (emphasis added).”**

**It is unclear whether Dr. Marsch obtained the didactic training required in 10 CFR 35.392(c)(1) - please provide sufficient information to enable us to verify that Dr. Marsch completed this training and please note that the didactic training she acquired for 10 CFR 35.100 and 35.200 authorization does not count for didactic training under 10 CFR 35.392.**

**Please refer to the regulatory requirements in 10 CFR 35.392, 35.57, 35.13 and 35.59, 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 written response to demonstrate that Dr. Marsch’s training and experience meet the appropriate regulatory requirements for the modality she seeks authorization for.**

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

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).

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,

A handwritten signature in black ink that reads "Colleen Carol Casey". The signature is written in a cursive, flowing style.

Colleen Carol Casey  
Materials Licensing Branch

License No. 13-18879-01  
Docket No. 030-17305

Enclosure:

Amendment No. 40