



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
JUN 08 2007

Jacek Wierzbicki, M.D.
Radiation Safety Officer
St. Mary's of Michigan Medical Center
800 S. Washington Street
Saginaw, MI 48601

Dear Dr. Wierzbicki:

Enclosed is Amendment No. 60 to your NRC Material License No. 21-03646-03 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. My fax numbers are either (630) 829-9782 or (630) 515-1259.

Please note that, at this time, I was unable to approve Dr. Shahzad Sadiq as an authorized user for the use of materials in 10 CFR 35.100, 35.200 and 35.300 and Dr. Tushar Shah as an authorized user for the use of materials in 35.600, limited to iridium-192 in an HDR remote afterloading brachytherapy device, because the information in your letter received March 12, 2007, and letter dated May 16, 2007, was insufficient to complete my review.

If you wish to pursue these requests please submit the information requested below and address it to my attention as "additional information to control number 316088."

1. Shahzad Sadiq, M.D. was not approved as an authorized user for the use of materials in 10 CFR 35.100, 35.200 and 35.300 because the supporting information provided did not demonstrate his compliance with the training and experience criteria in 10 CFR 35.13, 35.57, 35.190, 35.290 and 35.390.

Specifically, Dr. Sadiq was not listed as an authorized user on either of the referenced licenses provided in your letter dated May 16, 2007.

Please refer to 10 CFR 35.190, 35.290, 35.390, 35.13, 35.14, 35.57 and 35.59, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 1, for assistance in preparing your response. If necessary, please refer to our newly revised Forms 313a at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627.pdf>

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 responding to the above items, 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 do not submit extraneous documents.

- 2. Tushar Shah, M.D. was not approved as an authorized user for the use of materials in 35.600, limited to iridium-192 in an HDR remote afterloading brachytherapy device, because the supporting information provided did not demonstrate his compliance with the training and experience criteria in 10 CFR 35.690.**

Please refer to 10 CFR 35.690, 35.13, 35.14, 35.57 and 35.59, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 1, for assistance in preparing your response. If necessary, please refer to our newly revised Forms 313a at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627.pdf>

Specifically, I could not verify that Munther Ajlouni, M.D. was an appropriately qualified authorized user/preceptor for Dr. Shah under the referenced license given, 21-04109-16, Henry Ford Hospital, because this license is a broad scope license in which the Radiation Safety Committee evaluates and approves/disapproves authorized users internally. Authorized users are not listed on this license.

Please submit a currently signed and dated letter from the Radiation Safety Committee Chairperson for Henry Ford Hospital stating that Dr. Ajlouni was an authorized user for the HDR remote afterloading modality and during the specific timeframes when Dr. Ajlouni trained Dr. Shah.

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 responding to the above items, 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 do not submit extraneous documents.

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.

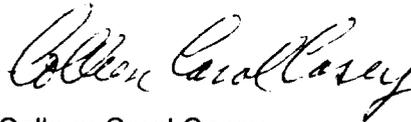
The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions

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>

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. 21-03646-03
Docket No. 030-02031

Enclosure:

Amendment No. 60