

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD LISLE, ILLINOIS 60532-4352

MAR 1 0 2005

Dennis R. Szmania, M.S. Radiation Safety Officer Munson Medical Center 1105 Sixth Street Traverse City, MI 49684-2286

Dear Mr. Szmania:

Enclosed is Amendment No. 36 to your NRC Material License No. 21-08317-01 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.

A. Please note that we did not approve your proposed authorized users, Drs. Holmes, Richmond and Kennell, either in whole or in part, at this time because the information provided in your letter dated December 1, 2004, was insufficient to complete our review.

If you wish to pursue these requests please submit the information below as a written response, addressed to my attention as "additional information to control number 313991." We will then continue our review.

1. Dr. Ryan Holmes was not approved as an authorized user for the use of materials in 10 CFR 35.300 because his preceptor statement did not adequately support his application for this type of use in order to completely meet the requirements in 10 CFR 35.390 or 35.930.

Specifically, we could not verify the credentials of his preceptor, Dr. Kastytis C. Karvelis, based upon the information given on the preceptor form. The referenced license for Dr. Karvelis, for Henry Ford Hospital, 21-04109-16, is a broad scope license that does not include the names of specific authorized users. The Radiation Safety Committee for that license evaluates and approves/disapproves of authorized users internally.

Please submit a letter currently signed and dated by either the RSO or the RSC Chairperson for Henry Ford Hospital attesting that Dr. Karvelis was an authorized user for materials in 10 CFR 35.300 under license no. 21-04109-16, during the specific, designated time frames when Dr. Holmes was trained.

Please do <u>not</u> 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

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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."

2. Lafayette Richmond, M.D. was not approved as authorized user for the use of materials in 10 CFR 35.100 and 35.200 because his specialty board certification was conferred in February 1996, which is more than 7 years previous to the date of application, December 1, 2004. Therefore, Dr. Richmond's training and experience do not demonstrate compliance with 10 CFR 35.59, "Recentness of training."

<u>Please submit</u> information demonstrating that Mr. Taylor has obtained related continuing education and/or work experience, in the uses of materials which he is requesting authorization for, since the required training and experience, i.e., specialty board certification, was completed.

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, Final, for assistance in preparing your response.

Please do <u>not</u> 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."

3. Todd Kennell, M.D. was not approved as authorized user for the use of materials in 10 CFR 35.100 and 35.200 because his specialty board certification was conferred in November 1992, which is more than 7 years previous to the date of application, December 1, 2004. Therefore, Dr. Kennell's training and experience do not demonstrate compliance with 10 CFR 35.59, "Recentness of training."

<u>Please submit</u> information demonstrating that Mr. Taylor has obtained related continuing education and/or work experience, in the uses of materials which he is requesting authorization for, since the required training and experience, i.e., specialty board certification, was completed. I noted that Dr. Kennell served as a Director of MRI at the Middleton VA Hospital from 1993 through 2000 and from

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2000 to the present.

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, Final, for assistance in preparing your response.

Please do <u>not</u> 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."

B. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically 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 enclosed license document is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability.

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. 21-08317-01 Docket No. 030-02074 D. Szmania

Enclosure: Amendment No. 36

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