



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

DEC 17 2007

Won Chae, M.D.  
Radiation Safety Officer  
Millennium Diagnostic Center  
28625 Northwestern Highway  
Suite 150  
Southfield, MI 48034-5741

Dear Dr. Chae:

Enclosed is Amendment No. 10 to your NRC Material License No. 21-32035-01 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 Drs. Marcel Zughaib and Jamal Zarghami for the use of materials in 10 CFR 35.100, limited to cardiovascular clinical procedures and Dr. Harry Shevitz for the use of materials in 10 CFR 35.100 and 35.200 at this time because the information provided in your letter dated November 28, 2007, 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 316727." We will then continue our review.**

- 1. Drs. Zughaib and Zarghami were not approved as authorized users for the use of materials in 10 CFR 35.100, limited to cardiovascular clinical procedures because no information was provided to support their applications for this type of use. Specifically, no information demonstrating that each physician met the requirements in 10 CFR 35.190, 35.57, 35.59, 35.13 and 35.14 was included with the letter.**

**Please refer to the above regulatory requirements, as appropriate, 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.**

**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."**

2. **Dr. Shevitz was not approved as an authorized user for the use of materials in 10 CFR 35.100 and 35.200 because no information was provided to support his application for these types of use. Specifically, no information demonstrating that Dr. Shevitz met the requirements in 10 CFR 35.190, 35.290, 35.57, 35.59, 35.13 and 35.14 was included with the letter.**

**Please refer to the above regulatory requirements, as appropriate, 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.**

**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."**

3. **Please note that we have reformatted Subitem Nos. 6.B., 7.B., and Condition No. 12. at this time to remove all references to excluded authorizations, such as "generators, xenon-133, aerosols, cardiovascular clinical studies, etc."**

**Please be reminded, however, that you are still bound by the restrictions imposed by the excluded authorizations contained in documents incorporated into your license in Condition No. 14 of your license.**

- B. 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 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 cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey  
Materials Licensing Branch

License No. 21-32035-01  
Docket No. 030-34561

Enclosure:

Amendment No. 10