



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

APR 06 2007

James Fitzsimmons, M.D.
Radiation Safety Officer
Medical Plaza Imaging Associates
Medical Plaza III Building, Suite 1400
4321 Washington Street
Kansas City, MO 64111

Dear Dr. Fitzsimmons:

Enclosed is Amendment No. 08 to your NRC Material License No. 24-26475-01 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.

Please note that we were unable to approve Michael Malis, M.D. as an authorized user for the use of materials in 10 CFR 35.100, 35.200 and 35.300 at this time because the information in your letter dated March 14, 2007, was insufficient to complete our review.

If you wish to pursue this matter, please submit the following information, addressed to my attention and referenced as "additional information to control number 315966."

Dr. Malis was not approved as an authorized user for the use of materials in 10 CFR 35.100, 200 and 35.300 because his training and experience did not appear to meet the requirements in 10 CFR 35.190, 35.290, 35.390, 35.57, 35.13 and 35.59, as appropriate.

Please note that the copy of the referenced license submitted for Dr. Malis was incomplete and it was a broad scope license, as well, which does not list authorized users specifically on the license.

In addition, the supporting letter from Dr. James W. Fletcher did not state that Dr. Malis was, in fact, an authorized user under the referenced license, No. 13-02752-03, as required by 10 CFR 35.13 and 35.57, as appropriate. Dr. Fletcher's letter also states that Dr. Malis' training and experience in 10 CFR 35.300 was limited to the "diagnosis of thyroid function and for treatment of hyperthyroidism in at least 15 patients," which does not qualify him for the use of materials in 10 CFR 35.300 for thyroid cancer ablation therapy, etc. This last restricted modality is not authorized by your license anyhow.

It may be to your advantage to obtain a letter currently signed and dated by either the RSO or the RSC Chairperson for License No. 13-02752-03 attesting that Dr. Malis was or is an authorized user for materials in 10 CFR 35.100, 35.200 and 35.300 (excluding thyroid cancer therapy), including the date(s) of authorization. Such a letter may assist in the review of Dr. Malis' application to become an authorized user under this license.

Please refer to the regulatory requirements in 10 CFR 35.190, 35.290, 35.390, 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. 1, for assistance in preparing your written response to demonstrate that Dr. Malis's training and experience meet the appropriate regulatory requirements for the modalities he 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\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

In addition, since Dr. Malis is certified by a medical specialty board that we no longer accept, 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.

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for an application for medical use must be the licensee's management, as required by 10 CFR 35.12(a).

Please note that we have reformatted Subitem Nos. 6.B. and 7.B. at this time to remove all references to excluded authorizations, including but not limited to authorizations such as "generators, xenon-133, aerosols, 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. 15 of your license.

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025, ext. 9841.


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,



Colleen Carol Casey
Materials Licensing Branch

License No. 24-26475-01
Docket No. 030-33080

Enclosure:

Amendment No. 08