



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

MAY 17 2007

Gregg Warren, D.O.
Radiation Safety Officer
Huron Valley-Sinai Hospital
1 William Carls Drive
Commerce, MI 48382-2201

Dear Dr. Warren:

Enclosed is Amendment No. 28 to your NRC Material License No. 21-24652-01 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 Rajiv Patel, M.D. as an authorized user for the use of materials in 10 CFR 35.300 at this time because the information in your letter dated February 12, 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 316029."

Dr. Patel was not approved as an authorized user for the use of materials in 10 CFR 35.300 because the referenced license submitted in support of his/her training and experience did not list Dr. Patel for the use of materials in 10 CFR 35.300. Therefore, it does not appear that Dr. Patel meets the requirements in 10 CFR 35.35.390, 35.57, 35.13 and 35.59, as appropriate.

Please refer to the regulatory requirements in 10 CFR 35.35.390, 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. Patel's training and experience meet the appropriate regulatory requirements for the modality s/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, if Dr. Patel 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.

Please refer to RIS 2005-31 at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf>

A hard copy of this document should have been sent to you already. Please refer to Table 1, Attachment 2, page 19 of 19, especially and note the activity thresholds listed for materials commonly included in 10 CFR 35.400.

At this time please specify which manufacturer's names/model numbers and possession limits you want for each radionuclide listed in Subitem Nos. 7. and 8. D and E. We must now review license applications and prepare license documents in accordance with this RIS and the requested information is necessary to complete that review. You may reference this as "additional information to control number 316029" and put it to my attention.

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 No. 7.B. and Condition No. 12. 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.

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. 21-24652-01
Docket No. 030-29063

Enclosure:

Amendment No. 28