



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

JAN 25 2008

Randall J. Phillips, M.D.
Radiation Safety Officer
QHG of Indiana, Inc.
7950 West Jefferson Blvd.
Fort Wayne, IN 46804-1677

Dear Dr. Phillips:

Enclosed is Amendment No. 58 to your NRC Material License No. 13-01535-01 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 Amit Sanghvi, M.D. as an authorized user for the use of materials in 10 CFR 35.100 and 35.200 at this time because the information in your letter dated October 15, 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 316638."

Dr. Sanghvi was not approved as an authorized user for the use of materials in 10 CFR 35.100 and 35.200 because Dr. Sanghvi has a specialty board certification that we do not accept and a portion of his 313a (AUD) forms was left blank, section 3b, which corresponds to the requirements in 10 CFR 35.290(c)(1)(ii). Other issues with the preceptor forms were also identified, as discussed below.

Your preceptor attestation for Dr. Sanghvi shows some irregularities. The only section you marked for yourself as an Authorized User is "35.390 + generator experience." But you are authorized on this license for materials in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11. Also, the license number given corresponds to this license, "QHG of Indiana, Inc." but on the form you attribute it to "Lutheran Hospital of Indiana." Please explain and correct these discrepancies on a revised, currently signed and dated 313a form for Dr. Sanghvi.

Please also obtain a preceptor Authorized User physician from The Western Pennsylvania Hospital to support Dr. Sanghvi's application, in addition to Ms. Margaret Blackwood, whose October 22, 2007, letter failed to include the timeframe when Dr. Sanghvi took his training at the Western Pennsylvania Hospital. Ms. Blackwood, while the Radiation Safety Officer, is not qualified as an Authorized User physician to serve as a preceptor.

As a result of these issues, it does not appear that Dr. Patel currently meets the requirements in 10 CFR 35.35.190, 35.290, 35.57, 35.13 and 35.59, as appropriate.

Please refer to the regulatory requirements in 10 CFR 35.190, 35.290, 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. Sanghvi's training and experience meet the appropriate regulatory requirements for the modality 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)

The following links may assist you also as they provide guidance for the completion of the 313a forms:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627sup1.pdf>

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

In addition, as Dr. Sanghvi is certified by a medical specialty board that we no longer accept, you may find the the following links and guidance in RIS 2003-17 helpful, found on our website:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

I noted that a Curriculum Vitae was submitted in support of Dr. Sanghvi's application. 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.

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).

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,



Colleen Carol Casey
Materials Licensing Branch

License No. 13-01535-01
Docket No. 030-01594

Enclosure:

Amendment No. 58