



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

SEP 28 2016

Samir Parikh, M.D.
Radiation Safety Officer
Henry Ford Allegiance Health
205 N. East Avenue
Jackson, MI 49201

Dear Dr. Parikh:

Enclosed is Amendment No. 62 to your NRC Material License No. 21-00258-06 in accordance with your request.

In this amendment we deleted Condition Nos. 13 and 14, as they appeared on Amendment No. 61, because they current regulations superseded them and/or their requirements were added to the Preamble at the top of page 1 of your license. Your remaining Conditions have been reordered to accommodate these changes.

We corrected the date of the document in Condition No. 13A. to reflect the accurate date of February 4, 2011, instead of the incorrect February 4, 2001.

We also modified Subitem No. 9.C. and Condition No. 12.B. for Dr. Renuka Patel's authorization. It appears that a different reviewer changed her authorization to include "...35.300 (limited to the oral administration of sodium iodide I-131 for imaging and localization studies)."

This was incorrect. After conferring with you by telephone on September 28, 2016, it was agreed to remove this piece of Dr. Patel's authorization at this time, thus rendering the license correct again. If our understanding is incorrect or if Dr. Patel wishes to add this authorization, please contact me immediately at (630) 829-9841.

We regret for the two errors noted above, regarding the document date and Dr. Patel, and we apologize for any inconvenience they may have caused you.

We are unable to approve Usman Saeed Khokhar, M.D. for the authorization to use materials in 10 CFR 35.200 at this time because the information provided in your letter dated June 28, 2016, was insufficient to complete our review.

If you wish to pursue this request, please provide a complete, written response that is currently dated and signed by a senior management official for this license, pursuant to 10 CFR 35.12(a).

Please note that you, as the Radiation Safety Officer, may co-sign correspondence to us but our regulations require the signature of management, pursuant to 10 CFR 35.12(a).

Your written response should be addressed to my attention at the above address, as "additional information to control number 591389." We will then continue our review.

Dr. Khokhar's request to become an authorized user for materials in 10 CFR 35.200, including parentally administered materials, must be supported by the completion of an appropriate preceptor attestation form NRC 313A(AUD).

Although a signed preceptor attestation was submitted, it is incomplete because we are unable to verify the preceptor indicated, Dr. Noelle Mann, from a license for DH#455 New York State/Stony Brook New York.

Since New York is an Agreement State, NRC does not have jurisdiction over this license. Please submit a complete, current, unredacted, signed and dated copy of the license that Dr. Mann is an authorized user under.

In addition, if this license is a Type A broad scope medical license, the licensee's Radiation Safety Committee evaluates and approves/disapproves of authorized users internally. The names of specific authorized users will not appear directly on the license, if this is the case.

Please submit a currently dated, signed letter from the Chairperson of the licensee's Radiation Safety Committee or from the Radiation Safety Officer for this license, stating that Dr. Mann was an authorized user for the use of materials in 10 CFR 35.200 (or the Agreement State equivalent in New York) between which (please specify) dates.

Your response should be accompanied by a business style letter containing all of the information on Form NRC 313, or you may submit the completed and signed Form NRC 313.

Please refer to the regulatory requirements in 10 CFR 35.290, 35.59 and section 8.12, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your written response. Part V. on page D-3, second paragraph, in Appendix D describes the information we are requesting.

NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses," is available on our website at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>

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 do not resubmit what we have already received from you.

Please note also that it would be quite helpful for you to also include in your response your fax number and email address for our records, in order to have alternate means of reaching you, as the need arises.

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."

If you have any questions concerning this request for additional information, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078.

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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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.

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.

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.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

S. Parikh

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We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 21-00258-06
Docket No. 030-01990

Enclosure:

Amendment No. 62