

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

NOV 17 2013



Khuraam Rashid, M.D.  
Radiation Safety Officer  
St. Joseph Mercy – Oakland  
44405 Woodward Avenue  
Pontiac, MI 48341-5023

Dear Dr. Rashid:

Enclosed is Amendment No. 60 to your NRC Material License No. 21-11651-01-01 in accordance with your request. Please note that the major 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, at this time, we must effect two changes to your authorizations in Subitem Nos. 6 through 9, C, D and E, inclusive.**

**Please submit a written response to enable us to effect these changes within 30 days of the date of this letter (about the third week of December 2013). Please address your response to my attention as "additional information to control number 581594.)"**

**If a different timeframe is necessary, please contact me at (630) 829-9841 to discuss alternative arrangements.**

- 1. First, we must change Subitem No. 8.C. of your license so that it shows one total possession limit for all materials permitted by 10 CFR 35.300. Subitem No. 8.C. currently shows "As needed (not to exceed 1 curie of iodine-131)."**

**Please specify one total possession limit for all materials permitted by 10 CFR 35.300. Your possession limit should be realistic for your needs and circumstances and include activity factored into waste streams for decay-in-storage.**

The enclosed document contains sensitive security-related information.  
When separated from this cover letter this letter is uncontrolled.

K. Rashid

- 2 -

2. Second, for materials in 10 CFR 35.400, we will need *individual possession limits for each radionuclide*. For example, you may break it out and request 500 millicuries for iodine-125 seeds, 500 millicuries for palladium-103 seeds, and three curies for cesium-131, and so on. You need only provide possession limits for radionuclides you are already approved for, as they are listed in Subitem 7.D and 7.E. If you wish to add other radionuclides, we will need full information for each, including the manufacturer's name and model no. of each sealed source.

- B. This also refers to your letter dated August 13, 2013, which requests authorization for Rojanandham Samudrala, M.D. for the use of materials in 10 CFR 35.100, 35.200 and 35.300; and for Frank Vicini, M.D., Larry Kestin, M.D., Mihai Ghilezan, M.D., John Vito Antonucci, M.D., and Alvaro Martinez, M.D. as authorized users for materials in 10 CFR 35.400.

Please note that we were unable to approve these physicians as authorized users because the information provided in your letter dated August 13, 2013, was insufficient to complete our review.

If you wish to pursue these matters, please provide a complete, written response that is currently dated and signed by a senior management official for your license, addressed to my attention at the above address, as "additional information to control number 581594." We will then continue our review.

1. An attachment to your letter dated August 13, 2013, included documentation intended to support Dr. Samudrala's application by virtue of his having been named an Authorized User (AU) for the requested modalities on the limited scope license for St. John Hospital and Medical Center (St. John's). The St. John's license is authorized to name its own authorized users internally.

However, I recently spoke with St. John's RSO, Laura Smith, regarding Dr. Samudrala's application to become an authorized user for a different license, again using the St. John's authorization as a qualifying credential. I advised Ms. Smith that, based upon the information that she and requesting licensee provided, it did not appear that Dr. Samudrala was qualified for the modalities requested. This was due, in part, to his specialty board certifications being unacceptable under NRC's current regulations.

Ms. Smith advised me that Dr. Samudrala may be discontinuing performance of his duties.

Since we cannot approve Dr. Samudrala as an authorized user currently and as it appears that he is considering discontinuation of his duties, please contact me if you wish to pursue adding him to this license for additional information.

Additionally, please note that the documentation provided in support of Dr. Samudrala's application from St. John's was insufficient to complete our

K. Rashid

- 3 -

review. Please refer to Appendix D to NUREG 1556, Vol. 9, Rev. 2, which contains guidance for the completion of Forms NRC 313a.

2. We were unable to approve Drs. Vicini, Kestin, Ghilezan, Anotnucci and Martinez for the use of materials in 10 CFR 35.400 because the only qualification presented on the referenced license no. 21-26488-01 was for their use of materials in 10 CFR 35.600, limited to iridium-192 in a high dose rate remote afterloading brachytherapy device (HDR).

Please note that NRC's regulations, including 10 CFR 35.13, 35.57 and 35.490, do not permit authorization for HDR as a qualification for materials in 10 CFR 35.400.

Please refer to the regulatory requirements in 10 CFR 35.490 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.

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 any documents you have already submitted.

- C. Please 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."
- D. Please also note that we deleted Condition No. 13, as it appeared on the corrected copy to Amendment No. 59, because this condition was no longer necessary.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

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

K. Rashid

- 4 -

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.

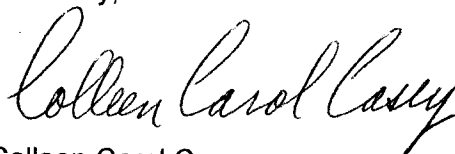
Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

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>.

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,



Colleen Carol Casey  
Materials Licensing Branch

License No. 21-11651-01

Docket No. 030-02104

Enclosure:

Amendment No. 60 |