



[REDACTED]

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

APR 25 2016

Edward Clayton  
Chief Executive Officer  
Phelps County Regional Medical Center  
1000 West Tenth Street  
Rolla, MO 65401

Dear Mr. Clayton:

Enclosed is Amendment No. 44 to your NRC Material License No. 24-18295-01 in accordance with your request.

Please note that the major changes made to your license are printed in **bold** font, including the reformatting of ADAMS accession numbers for all documents listed in Condition No. 14 of your license.

We have noted the requested change in your letter dated February 15, 2016, to have future NRC correspondence sent to you, Mr. Clayton, as CEO. We are sending a "cc" copy with enclosure to Dr. Downey, your RSO, also. We normally send correspondence to the attention of the RSO for each licensee by default and our databases and processing systems are designed to track the RSO by name and function. However, we cannot guarantee that this mechanism of sending correspondence to your attention will always work. Thank you for your understanding and patience in these matters.

We are unable to approve Nadeem Khan, M.S. and Albert de Sousa Zacarias, Ph.D. as Authorized Medical Physicists (AMPs) for your high dose rate remote afterloading brachytherapy program because the information in your letter dated February 15, 2016, was insufficient to complete our review. Your requests for their authorizations have been excluded from Condition No. 14.

If you wish to pursue these requests, please prepare a written response transmitted with a "business-style" letter identifying your license, similar to the style of your February 15, 2016, letter, addressed to my attention as "additional information to control number 590263."

Your letter must be currently dated and physically signed in a legible manner by a senior management official. *All correspondence to us must be signed, without exception.*

The information below for each proposed AMP must be completely addressed in order for us to continue our review and consider your requests.

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

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

[REDACTED]

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."

1. Nadeem Khan, M.S. was not approved as an AMP for several reasons:

His application relied on the alternate pathway in 10 CFR 35.51(b) for his education, training and experience, when a much simpler approach using his specialty board certification should have been followed. This is because his specialty board certification is acceptable for AMP purposes, as is evident on our medical licensing toolkit website.

In Part II of his Preceptor Attestation, First Section, the second option was marked instead of the first (board certification). Sections Two, Three and Four appear to have been completed appropriately.

However, we received two copies of Part II, one of which was unsigned by the preceptor and one which was signed. Only one copy, the signed one, should have been submitted.

In addition, the license that the preceptor references is unnamed; only some license numbers are given, which appear to be in the State of New York, an Agreement State. This poses several problems.

- a. NRC has no jurisdiction over Agreement State licenses so we have no way of verifying Mr. Vaughan as an appropriate preceptor for Mr. Khan.
- b. The license numbers given are ambiguous - are they for Mr. Vaughan only, are they for one or more licensed facilities?

Please note that NRC does not accept state-licensed physicists in 10 CFR Part 35, including 10 CFR 35.2 and 10 CFR 35.51, so this credential, if it is for Mr. Vaughan as a state-licensed physicist, has no meaning in this context.

Please identify the specific names of the licensed facilities that correspond to the New York license numbers given by Mr. Vaughan. On the education, training and experience sections of Mr. Khan's application, three different facilities are named but Mr. Vaughan only claims to be an AMP on two of these, by license number. If he is not an AMP on the third license named, then he cannot be accepted as a supervising individual for that training.

Please provide complete, signed, dated and unredacted copies for each of these three licenses that clearly show Mr. Vaughan as an AMP, as appropriate. If there is a discrepancy and Mr. Vaughan is not listed as an AMP on one or more of these licenses, as it appears to have been claimed, please explain.

If one or more of these three licenses is also a broad scope license, which does not list AMPs on the license directly, please provide the information in NUREG 1556, Vol. 9, Rev. 2, Appendix D, Section V, especially the second paragraph. The

[REDACTED]

Radiation Safety Committee for broad scope medical licenses evaluates and approves/disapproves of Authorized Users and AMPs internally.

Please refer to the regulatory requirements in 10 CFR 35.51, 35.2 and section 8.14, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your written response to demonstrate that Mr. Vaughan is qualified to serve as Mr. Khan's supervising individual and preceptor.

---

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, copies or excerpts from RSC meeting minutes, etc.

2. Alberto de Sousa Zacarias, Ph.D. was not approved as an AMP for several reasons:

His application lacked the support of a complete, signed, dated and unredacted copy of the Agreement State license for the University of Louisville that shows it to be a broad scope license, including authorization for the use of HDR devices and showing that the Radiation Safety Officer (RSO) is Sarah Hughes, M.S., who signed the letter dated September 28, 2015.

Please provide a complete, signed, dated and unredacted copy of the Kentucky license for the University of Louisville that clearly shows it to be a broad scope license, including authorization for the use of HDR devices and showing that the RSO is Ms. Hughes.

Please also note that, although we did not rely on Part I, section 3.c. and Part II of the preceptor attestation forms for Dr. Zacarias, his forms would not have been acceptable. This is because Part I, section 3.c. was left completely blank and Part II was "signed" using a stamper, which is unacceptable. All signatures must be actually, physically applied and legible. This is provided for future reference use.

Please provide the information in NUREG 1556, Vol. 9, Rev. 2, Appendix D, Section V, especially the second paragraph. The Radiation Safety Committee (RSC) for broad scope medical licenses evaluates and approves/disapproves of Authorized Users and AMPs internally. Normally, the chairperson for the RSC, or in some cases the RSO, provides the letter requested.

Please refer to the regulatory requirements in 10 CFR 35.51, 35.2 and section 8.14, 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, copies or excerpts from RSC meeting minutes, etc.

[REDACTED]

[REDACTED]

E. Clayton

- 4 -

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.

If you have any questions or comments concerning this amendment, please contact me at (630) 829-9841. My fax number is (630) 515-1078.

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.

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>.

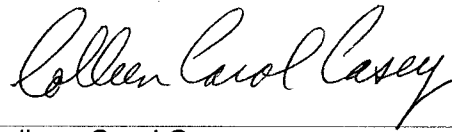
[REDACTED]

  
E. Clayton

- 5 -

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. 24-18295-01  
Docket No. 030-14804

Enclosure:  
Amendment No. 44

Cc w/enclosure:  
Edward Downey, Jr., D.O.  
Radiation Safety Officer

