



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

SEP 04 2019

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. 64 to your NRC Material License No. 21-11651-01 in accordance with your request.

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 please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

Please also note that we prepared this amendment using our new Web Based Licensing System (WBL). We deleted Condition No. 13, as it appeared on Amendment No. 63, in favor of adding reference to 10 CFR Part 71 in the Preamble language at the top of page 1 of your license.

We also added ADAMS accession numbers for the documents in the last condition of your license, new Condition No. 13, commonly known as "the tie-down condition." ADAMS is the NRC's electronic document system. More information on ADAMS, which NRC has been using for all official agency records since 1999, can be found on our website at: <https://www.nrc.gov/reading-rm/adams.html>.

We adjusted the type of document listed in Condition No. 13.B. from an "application dated October 27, 2010" to a "letter dated October 27, 2010," which is more correct.

We encountered some issues in the course of this review that your attention is directed to.

The letter dated May 31, 2019 ("the letter"), received in our offices on June 14, 2019, was signed illegibly by "Administrator St. Joseph Mercy Oakland" on hospital letterhead stationary. We do not know who this person is.

The letter requested the addition of Shehbaz H. Shaikh, M.D. as an Authorized User for the use of materials in 10 CFR 35.100, 35.200 and 35.300.

The only supporting information provided was the specialty board certification for Dr. Shaikh. There was no documentation indicating which state, if any, that he is licensed to practice medicine in, as required by 10 CFR 35.2, "Definitions," "Physician."

This one time, we were able to independently verify that Dr. Shaikh is licensed by the state of Michigan to practice medicine but we expect that kind of information to be provided in the original amendment request.

Dr. Shaikh only presented qualifications to support the use of materials in 10 CFR 35.100, 35.200, 35.392 and 35.394.

If it was your actual intention to only have him approved for these uses, you do not need to do anything further for his authorization.

In the future, please clearly align what you want physicians to become authorized for with what their qualifications allow them to do.

However, Dr. Shaikh was not approved for the use of materials in 10 CFR 35.396, which is also captured under 10 CFR 35.390.

If you wish to pursue authorization for Dr. Shaikh to include these materials, please provide only one response to the items below.

Please provide the information on Dr. Shaikh's training and experience to demonstrate that he meets the requirements in all of 10 CFR 35.390(b)(1), excepting 35.390(b)(1)(ii)(G)(1) and 35.390(b)(1)(ii)(G)(2); and 35.390(b)(2).

Here is a link to our website for these regulations: <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0390.html>

Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate, clearly identified senior management official) correspondence document, such as either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a.

Please ensure that the requested information is answered completely and accurately.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us. If you resubmit such information for the sake of adding context and other details to enhance its meaning, that is acceptable. Please do not send resumes or curricula vitae.

Please do not email a PDF document to me, and transmit a faxed version, and/or a hard copy sent by mail. Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors, although emailing a PDF document is the least efficient mechanism for responding to me.

The most reliable and fastest way to respond is to send a fax of one complete copy only to me at (630) 515-1078.

Please address your written response to my attention as "additional information to control number 612449" to facilitate proper handling in our offices.

The letter states "Please contact us if you have any questions concerning this request," but it does not provide the name of a point of contact, direct telephone numbers, fax numbers, or

email addresses. As noted above, the identity of the signatory is not shown legibly on this letter either.

Please always provide the name, direct telephone number, fax number and email address for at least one individual knowledgeable in the amendment being requested.

To assist you in the preparation of future licensing correspondence, the following information is being provided for future reference "as needed."

Please be reminded that the USNRC is an independent and objective federal government regulator.

This is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence with our licensees to achieve an improved working understanding of our respective roles in the licensing process.

This is not intended to be "all-inclusive", nor is it a substitute for your reviewing our regulatory requirements and guidance as they apply to your particular license and situation and preparing your licensing requests in accordance with them.

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."

What 10 CFR 30.9(a) means, in part, is that you, as the licensee, are primarily responsible for the quality of your submissions to NRC, as well as the completeness and accuracy of all information provided.

You, the licensee, are responsible for checking and verifying that the information you provide supports the requests you make to your license and that the requests you make to your license are complete, accurate and in alignment with our regulations and guidance.

Please do not expect NRC to perform the first check and verification of your licensing requests. We perform the regulatory authority verification that the information needed to consider your requests has been completely provided.

We noted that the issues we encountered with this amendment and the letter dated May 31, 2019, should have been readily apparent if a first check and verification had been performed prior to its submission.

It is understandable and expected that, occasionally, some minor additional information must be solicited from a licensee in the course of the review process.

But such occurrences should be rare and exceptional and address primarily minor issues, information that could not have been foreseen or planned around, etc.

It should not be routine and addressing basic issues that have been codified in our regulations for many years and which have been discussed in ample detail in our guidance documents, regulatory issue summaries, information notices, information on our website, and brought to your attention in previous deficiency and cover letter correspondence.

Your assistance in these matters is greatly appreciated and enables us to serve you, and all of our licensees and applicants, better and in a more timely fashion.

To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.

An applicant's or licensee's legal representative, administrative assistant, outside consultant, etc. will not suffice as a certifying officer.

As enumerated below, for all materials applicants and licensees, and as noted for medical/human use applicants and licensees, all initial requests for licensing requests must be signed, in order to comply with the regulatory requirements listed below.

If a certifying officer/management representative signs an "initial" licensing request that names someone else as a "point of contact," then the designated point of contact may be the sole signatory for any written responses related to that initial licensing request only, unless the NRC reviewer requests otherwise.

All subsequent "new/initial" licensing requests must then be signed appropriately.

Please always sign every licensing document and communication submitted, even if you sign an email and transmit it to us via email/PDF or fax, although signing an email is discouraged unless no other option is available at the time.

Sending us an email and/or a fax and/or a hard copy mailed document are simply "means of transmission" and not a substitute for an appropriate signatory on the actual documents being transmitted.

Unsigned email messages, electronically generated or imposed "signatures," stamped signatures, etc. are not acceptable substitutes for an actual, physically hand-written legible signature.

Submitting any licensing correspondence without a signature, or with an unacceptable signature, may delay the review process until an acceptable signature is obtained on the document(s) in question.

Please be reminded that 10 CFR 30.32(a) and (c) require:

"(a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter." And,

"(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf."

Please note that the NRC Form 313 requires the typed or printed name and signature of a certifying officer. The NRC Form 313 can be found at:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf>

If the NRC Form 313 is not used, then a business letter containing all of the information on the NRC Form 313 may be used instead.

For medical/human use applicants and licensees:

10 CFR 35.12 Application for license, amendment, or renewal requires:

“(a) An application must be signed by the applicant's or licensee's management.”

10 CFR 35.2, “Definitions” states, in part:

“Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.”

In accordance with 10 CFR 2.390 of the NRC's “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders,” 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 component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website 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.

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,

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

Colleen Carol Casey
Materials Licensing Branch
Region III

Docket No.: 030-02104
License No.: 21-11651-01

Enclosure:
Amendment No. 64