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

DEC 14 2017

Christopher M. Durbin, Ph.D.
Radiation Safety Officer
St. Luke's Hospital
232 S. Woods Mill Rd.
Chesterfield, MO 63017

Dear Dr. Durbin:

This refers to your letter dated September 12, 2017, received September 19, 2017, and your letter dated September 12, 2017, received September 29, 2017. These letters continue a request to add Jason M. Edwards, M.D. to your license as an authorized user (AU) for materials in 10 CFR 35.300, 35.400 and 35.600, (limited to iridum-192 in a high dose rate (HDR) remote afterloading brachytherapy device, that began with your letter dated May 25, 2017.

This also refers to the telephone discussion on December 13, 2017, between you and me concerning the items contained in this request for additional information.

As discussed, we have voided this request until we receive an appropriate written response that addresses the issues below. "Void," as used here, simply refers to an internal NRC administrative procedure that takes this request out of our active database queue. We will reactivate it and continue our review upon receiving your written response.

In our telephone call, you and I also resolved an apparent misunderstanding concerning the appearance of your signature on the letter dated September 12, 2017, received September 19, 2017. This letter was transmitted via facsimile. You affirmed that this letter was, in fact, physically signed by you and did not contain an electronic, digital signature. It only appeared that way to me as a result of the artifact-quality of the facsimile transmission. I apologize for this error and for any inconvenience it may have caused. I appreciate your cooperation in resolving this misunderstanding.

We are unable to approve Dr. Edwards as an AU at this time because the information in your letters above was insufficient to complete our review.

If you wish to pursue this authorization, please provide only one response to the items below. Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate 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. Please do not email a PDF document to us, 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.

Please address your written response to my attention as "additional information to control number 600950" to facilitate proper handling in our offices.

1. It appears that the Agreement State license that Dr. Kudrimoti works under is a Type A broad scope license and, as such, it does not include the names of AUs on the license itself. The licensee's internal Radiation Safety Committee (RSC) evaluates and approves or disapproves of AUs and maintains records of AUs.

   You have submitted a letter ostensibly from the University of Kentucky (U of K) that appears to indicate Dr. Kudrimoti is an AU for the use of materials equivalent to our 10 CFR 35.400.

   However, there is no identifying information at all in this letter indicating who it is from. No name and address, etc. of the author are given, it is not on letterhead, and it is not signed by anyone from the U of K.

   So please submit a currently signed, dated letter from the Chairperson of the licensee's Radiation Safety Committee attesting that Dr. Kudromoti is an AU under the U of K license for the use of materials in 10 CFR 35.400.

   This letter must also specify that Dr. Kudrimoti was an AU during the timeframe when Dr. Edwards was in training. If Dr. Kudrimoti has been as AU continuously since 2005, then please so state.

2. Regarding the letter from the U of K, we noted that it does not say that Dr. Kudrimoti is an AU for the use of materials in our equivalent of 10 CFR 35.392, 35.394, 35.396 and 35.690, limited to high dose rate remote afterloading brachytherapy devices.

   The letter mentions "HDR remote afterloader" but includes it under its equivalent to 10 CFR 35.400. High dose rate remote afterloading brachytherapy devices (HDR)s are not licensed un 10 CFR 35.400; they are licensed under 10 CFR 35.600, as they have been since 2002. There is no equivalence between 10 CFR 35.400 and 35.600.

   So it does not appear that Dr. Kudrimoti was an AU for HDRs under the U of K license. Please explain these discrepancies in your response and provide sufficient information to support Dr. Kudrimoti's assertion as an AU for 10 CFR 35.600, limited to iridium-192 in an HDR device.

   Also, the letter from the U of K does not state that Dr. Kudrimoti was approved by its Radiation Safety Committee (RSC) for the use of materials in 10 CFR 35.392, 35.394 and 35.396, or the Kentucky equivalents thereof.

   If Dr. Kudrimoti was not an AU for these modalities, then he could not and cannot serve as a supervising individual and preceptor for Dr. Edwards' training in these modalities.

   Please explain this discrepancy also in your response and provide sufficient information to support Dr. Kudrimoti's assertion as an AU for the modalities in 10 CFR 35.392, 35.394 and 35.396.

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, which is also the fastest way to transmit amendment requests and responses to requests from us for additional information.

My email address is colleen.casey@nrc.gov, which should not be used to transmit amendment requests and responses to requests from us for additional information, unless previously arranged with me personally. This is also the least reliable way to transmit amendment requests for a variety of reasons, unless, of course, it has been pre-arranged between you and me.

Please refer to the regulatory requirements stated above and the appropriate sections in NUREG 1556, Vol. 9, Rev. 2, especially Appendices B, D and E, for assistance in preparing your written response. In particular, Part II on page D-6, paragraph one and Section V. on page D-3, second paragraph in Appendix D reference some of the information we are requesting and describe preceptor statements and supporting licenses for preceptors. The following links may be helpful:

http://www.nrc.gov/materials/miau/med-use-toolkit.html

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

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

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.

You may also find it beneficial to review NRC Information Notice 2007 – 38: "Ensuring Complete And Accurate Information in the Documentation of Training and Experience For individuals Seeking Approval As Medical Authorized Users," which is located on our website at:

http://pbadupws.nrc.gov/docs/ML0722/ML072270127.pdf

This IN explains the importance and necessity of compliance with 10 CFR 30.9 and the potential consequences of non-compliance.

In our telephone call on December 13, 2017, you and I discussed some licensing issues related to this case and how NRC's licensing philosophy, structure and expectations factor into them. To facilitate your understanding, the following information may help to illuminate our discussion and the good points you made in that context. Your proposed AUs may also find this information useful.

The following is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence. USNRC is an independent and objective federal government regulator.

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.

In preparing your response, 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 this means, in part, is that the first vetting of any licensing request is expected to be made by the requesting applicant/licensee, against the regulations, license requirements and guidance involved. NRC's website also contains a great deal of well-organized information to assist medical use licensees, at our "medical licensing toolkit."

Only after the request has been thoroughly vetted by the applicant/licensee should the licensing correspondence be transmitted to NRC. This is the expectation that NRC uses to most efficiently process and review in a timely manner the many licensing actions received. The quality of the incoming request is a primary determining factor that only the applicant/licensee can control that enables NRC to serve and protect the public and the environment.

The technical quality, accuracy and completeness of your submission are primary factors that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process. Please only submit information that our regulations and guidance specifically address. Please completely and concisely answer questions that we ask and provide information that we specifically request.

Preparing your amendment requests carefully and in accordance with NRC's regulatory requirements and guidance, especially the documents in the NUREG 1556 series, as well as other information on our website at http://www.nrc.gov, will greatly help ensure that your correspondence is complete and accurate in all material respects, as 10 CFR 30.9 (a) requires it to be.

Please always include the name of at least one knowledgeable contact person who is familiar with your new license amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. A business email address for the contact person may also be helpful in many circumstances.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 24-01570-03
Docket No. 030-02305
Control No. 600950