



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

Scott M. Adams, BHS, CNMT
Radiation Safety Officer
Baptist Healthcare System
d/b/a Baptist Health Floyd
1850 State St.
New Albany, IN 47150

JAN 17 2018

Dear Mr. Adams:

This refers to the telephone discussion between you and me on January 17, 2018, concerning the additional information we requested of you in our letter dated December 4, 2017, for 4 proposed authorized users (AUs). In our call, you brought to my attention that I inadvertently did not include the deficient areas found with David Rodriguez's application to use materials in 10 CFR 35.100, 35.200, 35.392 and 35.394.

We apologize for this oversight and thank you for bringing it to our attention for inclusion at this time.

Please consider this as an additional request for additional information to the December 4, 2017, letter, based upon information provided in your letter dated August 3, 2017, received in our offices September 6, 2017, for Material License No. 13-12371-01.

- A. We were unable to approve David Rodriguez, M.D. as a new requested authorized user (AUs) for the use of materials in 10 CFR 35.100, 35.200, 35.392 and 35.394.

We were unable to approve Dr. Rodriguez as an AU for any of these modalities at this time because the information in your letter dated August 3, 2017, 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 600698" to facilitate proper handling in our offices.

1. The name of the State, Territory, or Commonwealth of the United States or District of Columbia in which Dr. Rodriguez is licensed to practice medicine, pursuant to 10 CFR 35.2, "Definitions," for the word, "Physician."

During our telephone discussion on January 17, 2018, you stated that it was your expectation that I, as a license reviewer, would "check a website" to see if your proposed AUs were licensed to practice medicine.

I responded that, under 10 CFR 30.9(a), "Completeness and accuracy of information,"... the following is the licensee's responsibility ..."(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."

Therefore, such activity falls outside of the normal reviewing parameters. It is normally not necessary to check the websites of the 50 states and territories in the United States to research which state or territory has licensed a particular physician. Such information is normally provided by the licensee, in accordance with 10 CFR Part 35 and NUREG 1556 Vol. 9, Rev. 2.

2. Evidence that Dr. Rodriguez's training and experience complied with 10 CFR 35.290(c)(2); and 35.392(c)(2) and 35.392(c)(3); and 35.394(c)(3).
3. We noted that the license that Dr. Rodriguez's apparent preceptors/supervising individuals worked under is an Agreement State license that NRC does not have access to.

Therefore, we were unable to verify, and, from the documents submitted, we were unable to even "identify" the physicians who served as supervising individuals and/or preceptor physicians.

Please include the names, terminal degrees and qualifications of Dr. Rodriguez's supervising individuals and preceptors; a complete, signed, unredacted copy of the Agreement State licenses they worked under; the modalities they were qualified as AUs for; and the timeframes when they served as supervising individuals and preceptors for each proposed AU.

Also, note that the Therapy Log provided is, "prospective" in that it states that "By the time of the ABR oral examination this applicant will have successfully completed the hours of training and experience outlined in 10 CFR 35.290, 35.392 and 35.394."

The actual hours of training and experience completed is not specified, nor is any of the specificity required by the regulations themselves, which is normally captured on the 313a series of Forms.

We cannot accept "prospective" data because, by definition, the training and experience has not happened yet. Training and experience must be "retrospective," in that it must "already have happened."

Further, the names of several different "preceptors (according to the form used)", were used to sign each therapy experience for Dr. Rodriguez.

But NRC has no way to know who these "preceptors" are, and verify their qualifications, as we are required to do. It is not even clear what the names of these "preceptors" are, whether they are physicians (only one of them listed a terminal medical degree). Also, see item B. below.

4. If the Agreement State license for Dr. Rodriguez's preceptor/supervising individual is also a Type A broad scope license, note that such licenses do 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.

For such Type A broad scope licenses, please submit a currently signed, dated letter from the Chairperson of the licensee's Radiation Safety Committee attesting that each proposed AU's supervising person(s) and preceptors were AUs. This letter must also specify the timeframe when the supervising person(s) and preceptors served as such for each proposed AU.

- B. In our telephone discussion, you stated that you thought that an Agreement state license naming Barry Scott Stevens, M.D. had been included with your letter dated August 3, 2017. I checked our records and found that we had not received a copy of a license naming Dr. Stevens as an AU. If or when you request that Dr. Stevens be considered to become an AU again, you may submit it in support of his application at that time.
- C. 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.

Appendix B contains blank 313a Forms for each type of authorized entity that NRC licenses for medical programs. Appendix D contains guidance to assist in the completion of these forms.

It is highly recommended that these forms be used routinely for all proposed AUs in order to correctly and completely capture the information NRC needs to consider in evaluating requests for proposed individuals against the regulatory requirements.

Please refrain from submitting extraneous documents that do not support the requested authorizations, i.e., "abbreviated" or "shorthand" style documents prepared in lieu of Forms NRC 313a for proposed AUs that often contain information summaries that fail to adequately address the regulatory requirements for training and experience. These summaries are often too compressed, generic and are presented in a "future" tense and context that makes them particularly unsuitable for evaluating the qualifications for a proposed AU of any type.

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 transmit amendment requests and responses to requests from us for additional information, unless previously arranged with me personally.

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,

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

Colleen Carol Casey
Materials Licensing Branch

License No. 13-12371-01
Docket No. 030-01659

Control No. 600698