



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

DEC 04 2017

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

Dear Mr. Adams:

Enclosed is Amendment No. 62 to your NRC Material License No. 13-12371-01 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 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.

- A. We were unable to approve 4 of the 5 new requested authorized users (AUs) in your letter dated August 3, 2017, received in our offices September 6, 2017. Your letter requested the addition of 3 proposed (AUs), Otis Kolvin, M.D., David Rodriguez, M.D. and Barry Scott Stevens, M.D., for the use of materials in 10 CFR 35.100, 35.200, 35.392 and 35.394. You also requested to add Ilana Kogan, M.D. as an AU for the use of materials in 10 CFR 35.100, 35.200 and 35.300.

We were unable to approve these 4 physicians as AUs 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 these authorizations, 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.

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

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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.

- B. We noted that the American Board of Radiology (ABR) certificate for Barry Scott Stevens, M.D. did not include the words "AU Eligible" above the seal. The words "AU Eligible" must appear above the seal on the actual certificate for the diplomate to be considered "board certified."

Therefore, according to NRC's website for specialty board certifications at <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html> Dr. Stevens is not considered to be board certified for NRC's purposes and he may not use this pathway to demonstrate compliance with the requirements in 10 CFR 35.290, 35.392 and 35.394. If you wish to pursue this matter, Dr. Stevens will have to apply to become an AU under an alternate pathway, as described in the regulations above. Also see the guidance mentioned below for assistance.

In addition, please specify the name of the State, Territory, or Commonwealth of the United States or District of Columbia in which Dr. Stevens is licensed to practice medicine, pursuant to 10 CFR 35.2, "Definitions," for the word, "Physician."

- C. There were several common missing and/or incomplete pieces of essential information for each of the remaining 3 proposed AUs, as follows.
1. The name of the State, Territory, or Commonwealth of the United States or District of Columbia in which each physician is licensed to practice medicine, pursuant to 10 CFR 35.2, "Definitions," for the word, "Physician."
 2. Evidence that each physician'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 licenses that each physician's apparent preceptors/supervising individuals worked under are all Agreement State licenses 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.

For each proposed AU, please include the names, terminal degrees and qualifications of their 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.

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4. If the Agreement State licenses for each of these 3 physicians are also Type A broad scope licenses, 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.
- D. Please clarify the spelling for Otis Kolvin, M.D. Your letter dated August 3, 2017, refers to him as "Kolvin" but the supporting documents you attached refer to him as "Colvin." Please advise us of the correct name spelling.
 - E. Dr. Kolvin's specialty board certification was obtained more than 4 years prior to the date of application. On NRC's website for specialty board certifications at: <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>, under 10 CFR 35.290, 35.392 and 35.394, for the American Board of Radiology certification it states, in part: "Additionally, the certificates issued from July 2012 forward will initially be recognized for 4 years from the date of issuance and after the 4-year period, the ABR web site needs to be checked to ensure that the individual is still certified. The ABR monitors the certification status of its diplomates and posts this information on its web site for all individuals including those certified after 2012."

Please check the ABR website for Dr. Kolvin and provide proof that his specialty board certification is still current, as of December 2017.
 - F. Please submit clarification as to which subsections of authorization under 10 CFR 35.300 Dr. Kogan is applying for. We cannot approve any new AU for all of 10 CFR 35.300 because there is no actual medical modality for 10 CFR 35.390(b)(1)(ii)(G)(4). Therefore, all new requests to become an AU must explicitly state which subsections are being applied for, such as 10 CFR 35.392, 35.394 and/or 35.396.

We attempted to evaluate Dr. Kogan's application as if it were for the uses in 10 CFR 35.392, 35.394 and 35.396, and we were still unable to approve the request.

In addition, the copy of iodine-131 therapy training that accompanied Dr. Kogan's application was too poor to read and we were unable to consider it for her application. Please prepare appropriate Forms NRC 313a for each modality that Dr. Kogan is applying to become an AU for. The blank forms are in NUREG 1556 Vol. 9, Rev. 2, Appendix B.

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.

- G. 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

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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.

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."

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.

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.

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

The following is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence.

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.

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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.

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.

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 note that your submission should not include extraneous documentation, which only serves to delay the review 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 also ensure that an appropriate senior management official (required by 10 CFR 35.12(a)) and/or your Radiation Safety Officer signs and dates the new license application or amendment request letter.

Please include the name of at least one knowledgeable contact person who is familiar with your new license application or 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.

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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 "Agencywide Documents Access and Management 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:

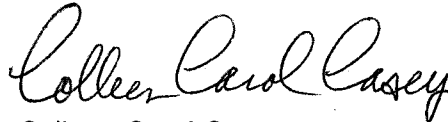
<http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

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

Enclosure:

Amendment No. 62