



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

AUG 26 2008

Kenneth W. Arnett, M.D.
Radiation Safety Officer
North Kansas City Hospital
North Kansas City, MO 64116

Dear Dr. Arnett:

This refers to your letters dated May 20, 2008, June 24, 2008, and August 6, 2008, concerning a request for amendment to your byproduct materials license no. 24-18628-01.

Please note that I am unable to approve Timothy Waltner, M.D., Christopher Formen, M.D. and Patrick O'Keefe, M.D. as Authorized Users (AU) at this time because the information in your correspondence above was insufficient to complete my review.

If you wish to pursue these requests, please submit the information requested below and address it to my attention as "additional information to control number 316909." We will then continue our review.

- A. Dr. Waltner wasn't approved as an AU for the use of materials in 10 CFR 35.100, 35.200 and 35.300 because his 313a Forms/preceptor attestation forms were left blank, incomplete and/or were filled out incorrectly and his application failed to support his request.**

Please review his preceptor forms against the requirements in 10 CFR 35.190, 35.290 and 35.390 and determine whether Dr. Waltner's training and experience, specialty board certification (check on our website at: <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>), clinical training and experience, and preceptor attestations are correctly and completely filled out and supported, as necessary.

Please note that I was unable to verify his preceptor's qualifications because the preceptor references an Agreement State license (that we do not have access to) that may also be a broad scope license, i.e., it does not name AU's on its license document directly; rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.

Please submit fully completed preceptor attestation forms, including training and experience, etc. for Dr. Waltner in accordance with 10 CFR 35.290 and 35.390.

Please review the guidance for the completion of these forms at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627.pdf>

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627sup1.pdf>

Please also submit a copy of the Agreement State License for the University of Kansas Hospital and, if appropriate, please also submit a letter currently signed and dated by the Chair of the Radiation Safety Committee stating which modalities Dr. Reginald Dusing was authorized for under the license and specifying the timeframes when he held said authorizations.

Please do NOT submit copies of minutes from the licensee's RSC meetings or other documents from the Agreement State licensee, esp. patient records, or extraneous documentation that we must protect, per 10 CFR 2.390.

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your response.

As Forms 313a will be used in support of your response, please use the revised Forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

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."

- B. Dr. Formen wasn't approved as an AU for the use of materials in 10 CFR 35.100, 35.200 and 35.392 because his 313a Forms/preceptor attestation forms were left blank, incomplete an/or filled out incorrectly and his application failed to support his request.

Please review his preceptor forms against the requirements in 10 CFR 35.190, 35.290 and 35.392 and determine whether Dr. Formen's training and experience, specialty board certification (check on our website at:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>), clinical training and experience, and preceptor attestations are correctly and completely filled out and supported, as necessary.

Please note that Dr. Formen's specialty board certification is not acceptable because it does not include the words "AU eligible" above the seal, although he passed the board on an otherwise acceptable date, June 14, 2006.

Please submit fully completed preceptor attestation forms, including training and experience, etc. for Dr. Formen in accordance with 10 CFR 35.290 and 35.392.

Please review the guidance for the completion of these forms at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627.pdf>

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627sup1.pdf>

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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."

- C. Dr. O'Keefe wasn't approved as an AU for the use of materials in 10 CFR 35.100, 35.200 and 35.392 because his 313a forms/preceptor attestation forms were left blank, incomplete and/or filled out incorrectly and his application failed to support his request.

Please review his preceptor forms against the requirements in 10 CFR 35.190, 35.290 and 35.392 and determine whether Dr. O'Keefe's training and experience, specialty board certification (check on our website at:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>), clinical training and experience, and preceptor attestations are correctly and completely filled out and supported, as necessary.

Please note that Dr. O'Keefe's specialty board certification is not acceptable because

the certificate itself was not submitted and the letter submitted does not state which specialty Dr. O'Keefe became certified in. Please submit a copy of the certificate itself.

Please submit fully completed preceptor attestation forms, including training and experience, etc. for Dr. O'Keefe in accordance with 10 CFR 35.290 and 35.392.

Please review the guidance for the completion of these forms at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627.pdf>

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627sup1.pdf>

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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."

As I cannot issue an amendment at this time, I am voiding your request until we receive an acceptable written response. A "void" simply takes your request out of our "active" database until an acceptable written response reactivates the request.

This action is without prejudice to resubmission. If you resubmit your request, please state that the resubmission is additional information to Control Number 317196 to facilitate proper handling and please reference your request to my attention.

K. Arnett

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If you have any questions or require clarification on any of the information stated above, you may contact me at (630) 829-9841.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey". The signature is written in black ink and is positioned above the printed name.

Colleen Carol Casey
Materials Licensing Branch

License No. 24-18628-01
Docket No. 030-13966