COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 515-1078

CONVERSATION RECORD | TIME | DATE

ACTUALLY FAXED? YES. **January 7, 2010**

NAME OF PERSON(S) CONTACTED | ORGANIZATION | TELEPHONE NO.

Patrick Byrne, Consultant for Dupont Hospital 1-877-317-5811 ext. 343
Fax: 1-317-581-1931

SUBJECT
License No.: 13-32291-01 Control No.: 318556

SUMMARY
We have reviewed your letter dated September 23, 2009, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

We cannot authorize Joseph F. Schneider, Jr., M.D. as an Authorized User AU of materials under 10 CFR 35.400, and we cannot authorize the addition of materials in 10 CFR 35.400 at this time, because the information in your letter dated September 23, 2009, was insufficient to complete our review.

Dr. Schneider could not be approved as an AU because the referenced license provided as an attachment to the September 23, 2009, letter does not name Dr. Schneider as an AU for the use of materials in 10 CFR 35.400, as requested in your letter.

Please refer to 10 CFR 35.13(b)(1) or 35.13(b)(4)(i), excerpted below:

"License amendments.

A licensee shall apply for and must receive a license amendment--

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but is not authorized on the licensee's current license issued under this part; except that—

(1) A Government agency or a Federally recognized Indian Tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.

(2) Except as provided in paragraph (a)(1) of this section, all other licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 may continue to use those materials for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a medical use license amendment

request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, **except--**

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), **35.490(a),** 35.590(a), and 35.690(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) and (c) and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist--

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy"

Dr. Schneider does not meet the regulatory requirements to become at AU based upon the information provided. Please submit appropriate documentation demonstrating that Dr. Schneider meets the requirements to become an AU for the use of materials in 10 CFR 35.400.

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.

If Dr. Schneider submits a medical specialty board certification please note that NRC does not recognize certain medical specialty board certifications. Please see this link on our Medical Licensing Toolkit page for a list of the medical specialty board certifications that we recognize:

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

In addition, if, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf

Please do not submit resumes, CV's, copies of Radiation Safety Committee meeting minutes or applications 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.

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

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

Also, please note that we will have to verify Dr. Schneider's preceptor if you resubmit his application with preceptor forms. If Dr. Schneider received his training at a broad scope medical institution and/or if the medical institution is located in an Agreement State, we will be unable to verify his preceptor's qualifications. This is because we do not have access to Agreement State licenses and broad scope licenses do not name Authorized Users (AU's) on the license document directly. Rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.

If appropriate, please submit the license number for Dr. Schneider's preceptor, if he trained at a medical institution in an NRC state and/or please submit a copy of the Agreement State License for the medical institution where Dr. Schneider trained. If Dr. Schneider's preceptor AU is a permit-holder on a broad scope license, please also submit a letter currently signed and dated by the Chair of the Radiation Safety Committee stating which modalities the preceptor AU was authorized for under the license and which timeframes s/he held said authorization.

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."

In either your response to the item below or in your next amendment request, please provide the facsimile telephone number that is best to reach you with in order to complete our records.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025.

We will be unable to continue processing your request until we receive this information. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

ACTION REQUIRED

As we cannot issue an amendment at this time we are voiding this request in order to enable you to prepare a quality application without time constraints. This is done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address using the control number 318556 to facilitate proper handling.

PLEASE NOTE THAT A "VOID" IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST "ON HOLD" (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA SUBMISSION OF A WRITTEN

RESPONSE. IT "BUYS" YOU TIME TO PREPARE A QUALITY RESPONSE AND IS OFTEN REGARDED AS A "GOOD THING."

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025, ext. 9841.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	January 10, 2010

NRC FORM 386 (RIII)
(4-2004)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 1/7/2010

NUMBER OF PAGES: 5
(including this page)

SEND TO: PATRICK BYRNE, MPC for

LOCATION: DUPONT HOSPITAL

FAX NUMBER: 1-317-581-1931 ☐ ***VERIFY BY CALLING SENDER***

FROM:
(SENDER) COLLEEN CAROL CASEY

TELEPHONE NUMBER: 630 - 829 - 9841 FAX NUMBER: 630 - -

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Please call me if you have any questions.

Thanks,

Colleen Carol Casey

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address , by U.S. Mail. Thank you.