

**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.

April 2, 2011

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

David Schmitt, R.Ph., RSO for Lakeview Diagnostic, LLC

810-987-3317

Fax: 810-987-4699

SUBJECT

License No.: 21-32444-01MD

Control No.: 574176

SUMMARY

We have reviewed your letter dated December 27, 2010, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

- 1. This letter requests adding Amanda M. Miller as an Authorized Nuclear Pharmacist. Ms. Miller submitted documentation that she completed a certificate program at Ohio State University between November 30, 2009 and December 23, 2009, inclusive, in which she fulfilled 254 hours of work, required by 10 CFR 35.55(b)(1)(i). she claims 214 hours of classroom work and 40 hours of practical work experience for a total of 254 hours.**

By my calculations this works out to Ms. Miller's working approximately 10.5 hours per day, every day, without a break, for 24 days, between Nov. 30 and Dec. 23, 2009. Such a schedule appears to be unusually rigorous.

Please have Ms. Miller and/or her preceptor or one of the signers of her certificate, such as George Hinkle, explain, in writing, whether my assumptions and calculations are correct. If they are not or if there is some other explanation, please provide that in writing, under a current date and signature.

- 2. We cannot verify Ms. Miller's preceptor, Eric H. Schaaf, of HeartLight Pharmacy in Ohio, because we do not have access to the licenses in the Agreement State of Ohio. They are not under NRC's jurisdiction. Please submit a complete, signed and dated copy of the HeartLight Pharmacy license demonstrating that Mr. Schaaf was an Authorized Nuclear Pharmacist (ANP) from May 2007 to the present. Due to the timeframe, it may be necessary to submit more than one copy to cover the period from May 2007 to the present.**

Please also clarify whether Mr. Schaaf was a registered pharmacist, as no "R.Ph." was included after his name on any of Ms. Miller's documents.

3. Please note that the wrong 313a forms were used by Ms. Miller to complete her application. The correct forms have been available for approximately 3 years + in NUREG 1556, Vol. 9, Rev. 2 and on our website at:

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

Please note that the 313a Forms have now been created as six different versions, each corresponding to a different type of authorized user, RSO or ANP, etc.

It is recommended that Ms. Miller and her preceptor complete the appropriate Form 313ANP and not leave anything blank, as it then appears to be overlooked. If a section is not applicable, please mark it as such.

It is also recommended that the document be filled out in its entirety and without reference to other documents, to ensure that complete information is provided. Otherwise, one runs the risk of having to resubmit additional information again.

Guidance in completing the forms is available in Appendix D to the same NUREG document and on our website at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/sr1556v9r2-final.pdf#app-d>

Ms. Miller's forms, as submitted, state, in part, that she was a "student intern worked on all aspects of the pharmacy with all of the isotopes." This is not an acceptable description of her experience. Please be specific in providing information about her work experience, in accordance with what the newer forms request, which correlate with our regulatory requirements.

4. Please submit a copy of Ms. Miller's diploma to verify completion of her degree and the date when it was conferred.

To assist you with the above, please refer to 10 CFR 35.559b)(1) and (2), available at:

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0055.html>

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>.

ACTION REQUIRED

As we are unable to approve of this amendment at this time, we are voiding it until such time as you provide an adequate written response. This is done without prejudice to the resubmittal of your request at a future date.

Please note that "void" means that we are taking it out of our active database until you reactivate it via a written response. This buys you more time to prepare an appropriate and complete response without time constraints.

Please submit the requested information as "additional information to control number 574176" and addressed to my attention to facilitate proper handling in our offices. Upon receipt of your response we will reactivate placement of your request in our database and resume our review. Address your written response to my attention at the above address.

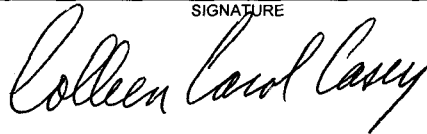
PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841. My fax number is 630-515-1078.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen Carol Casey



April 2, 2011

TRANSMISSION VERIFICATION REPORT

TIME : 04/02/2011 22:44
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE, TIME	04/02 22:44
FAX NO./NAME	88109874699
DURATION	00:00:56
PAGE(S)	04
RESULT	OK
MODE	STANDARD ECM

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:

4/2/11

NUMBER OF PAGES:
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4

SEND TO:

DAVID SCHMITT, R.Ph.

LOCATION:

LAKEVIEW DIAGNOSTIC

FAX NUMBER:

810-987-4699

VERIFY BY CALLING SENDER

FROM:
(SENDER)

COLLEEN CAROL CASEY

TELEPHONE NUMBER:

630-829-9841

FAX NUMBER:

630-515-1078

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MESSAGE

Please call me if you have questions. (These same



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REGION III
2443 Warrenville Road, Suite 210
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TELEFAX TRANSMITTAL

DATE: 4/2/11 NUMBER OF PAGES: 4
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SEND TO: DAVID SCHMITT, R.Ph.

LOCATION: LAKEVIEW DIAGNOSTIC

FAX NUMBER: 810 - 987 - 4699 VERIFY BY CALLING SENDER

FROM: COLLEEN CAROL CASEY
(SENDER)

TELEPHONE NUMBER: 630 - 829 - 9841 FAX NUMBER: 630 - 515 - 1078

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 questions. (These same deficiencies will also apply to Ms. Miller's application under the new license.)

Thank you.

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.