

**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
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ACTUALLY FAXED? YES.	3:25pm	Nov. 13, 2008
Transmitted on 11/18/08 for site visit on 11/20/08		

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO
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Katheryn LeBlanc, Pharm.D., proposed RSO for Pioneer Pharmacy	314-426-5290	<i>She received fax.</i>
	Fax: 314-426-5804	

SUBJECT

License No.: PENDING	Control No.: 317482
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SUMMARY

We have reviewed your application dated September 4, 2008, and your letter dated October 8, 2008, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. Please clarify the spelling of your first name. The letter dated Oct. 8, 2008, spells your first name two different ways: "Katheryn" in the letter and "Katherine" on the Louisiana license submitted in support of your becoming RSO for this license. Which spelling is correct?
2. Please name at least one Authorized Nuclear Pharmacist to your new license. It was not clear who the ANP(s) were supposed to be for this license. Please also advise me what to do with the information on Rita Gentilcore, M.S., R.Ph. as you are assuming her role as RSO. Your application refers to section 7.2 for the ANP designation but I could not locate this section.
3. One of the major problems with this application is that it requests a very broad range of authorizations and it does not support most of these requests with appropriate information. In my discussion with you on Nov. 13, 2008, you stated that you only intended to use Tc-99m and TI-201 initially.

Therefore, it appears to be beneficial to both you and the NRC to consider scaling down your requested authorized materials to only what you really need. You can always amend your license at a later date should the need arise. As I assume that this is what you will likely do, I will not go into detail in this record about deficiencies identified in the application for radionuclides requested other than Tc-99m and TI-201. In your response to this item, please specifically withdraw your request for authorization for radionuclides other than those you will specifically need.

Also, note that you may need to request certain sealed sources for calibration and reference tests on your instrumentation, depleted uranium shielding for generators and Mo-99 for generators.

4. Your facility diagram, as submitted, lacks sufficient detail to be acceptable. Please see NUREG 1556, Vol. 13, Rev. 1, section 8.9.1., including sample diagrams shown and resubmit your diagram in entirety. Please do not submit blueprints or copies of blueprints. Please show and describe locations of shielding (including types and thicknesses of shielding), the proximity of radiation sources to unrestricted areas and other items related to radiation safety.
5. Please provide a copy of the registration or license from the Missouri State board of Pharmacy as a pharmacy.
6. Your application included request for authorization of materials in 10 CFR 35.57(a). Please note that this is incorrect. 10 CFR 35.57(a) has no relevance to a request for authorized materials. Please discuss with me what, if any, regulatory reference may be appropriate or withdraw this request.
7. Item 10.12 of your application includes a request for authorization to use a new unit dose container, in addition to the containers you already use. Please note that I will not be "approving" this request as it is outside the scope of my review for your new license application. Please address only the information requested in section 8.10.12 of NUREG 1556, Vol. 13, Rev. 1. Please withdraw the "Evaluation of Shielded Syringe Carriers for Transporting Radioactive Doses," enclosed with your application.
8. **There appears to be only one personal monitoring station on your diagram but there appear to be three access points, all of which should have a personal monitoring station. Please clarify this finding.**
9. **Please describe how after-hours delivery persons will be permitted access to the drop-off area for packages but still prevented from accessing the rest of the licensed and restricted space in the lab.**

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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 (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).

ACTION REQUIRED

Submit the requested information within 10 calendar days (by Nov. 28, 2008) by referencing control number 317482 to facilitate proper handling. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address. review. Address your written response to my attention at the above address.

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If you cannot meet the requested response date please call me to arrange for an alternative date to respond.

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

NAME OF PERSON DOCUMENTING CONVERSATION

Colleen Carol Casey

SIGNATURE



DATE

Nov. 18, 2008



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

REVISED
PAGE

TELEFAX TRANSMITTAL

Please see new items 8+9.

DATE: 11-18-08

NUMBER OF PAGES: 1
(including this page)

SEND TO: KATHERYN LEBLANC

LOCATION: Pioneer Pharmacy

FAX NUMBER: 314-426-5804 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

This is primarily what we will discuss Thursday, in addition to usual Pre-licensing Site visit info.

I'm sorry - I left 2 items out of original submission by mistake.
Colleen Carol Casey

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.

TRANSMISSION VERIFICATION REPORT

TIME : 11/18/2008 15:28
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE, TIME 11/18 15:27
FAX NO./NAME 83144265804
DURATION 00:00:48
PAGE(S) 03
RESULT OK
MODE STANDARD
ECM

NRC FORM 386 (R11)
(4-2004)



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REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 11-18-08 NUMBER OF PAGES: 3
(including this page)

SEND TO: KATHERYN LEBLANC

LOCATION: Pioneer Pharmacy

FAX NUMBER: 314-426-5804 VERIFY BY CALLING SENDER

FROM: COLLEEN CAROL CASEY
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-575-1078

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MESSAGE

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