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: 4/3/11

NUMBER OF PAGES: 8
(including this page)

SEND TO: DAVE SMITH, R.Ph.

LOCATION: Lakeview Diagnostic LLC

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

FROM:
(SENDER) COLLEEN CASEY

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

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MESSAGE

Dave, lets discuss this at your earliest convenience, hopefully we can connect on Monday, 4/4/11.

Thank you!

Colleen Carol Casey

NOTICE

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

CONVERSATION RECORD | TIME | DATE

ACTUALLY TRANSMITTED? YES. **April 3, 2011**

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
David Schmitt, R.Ph., proposed RSO for Lakeview Diagnostic, L.L.C		810-987-3317 Fax: 810-987-4699

SUBJECT
License No.: PENDING Control No.: 574220

SUMMARY
We have reviewed your application dated December 27, 2010, (with attachments) and your letter dated December 27, 2010, requesting a new byproduct materials license and find that we need additional information as follows:

1. **I received voicemail messages from you and your consultant, Ray Carlson, a few days ago. I left a voicemail message for you at the Port Huron pharmacy phone number on the evening of April 2, 2011, requesting clarification about Ray's comment that you were "being evicted" from the Port Huron location, if I understood correctly. I also left my home phone number in the message, enabling you to contact me Sunday, April 3, 2011, if you chose to do so. I did not hear from you so I assume you either did not receive this message or you chose not to contact me today.**

2. **I'm very confused as to why this situation with the Port Huron location impacts getting the new license for the Harrison Township location.**

   I am also, of course, very concerned that the Port Huron location, which is licensed separately, will have an adequate facility to operate from.

   I will try to reach you Monday morning, April 4, 2011, to obtain clarification of these issues.

3. **The 313 form in your new license application package lists different mailing and location of use addresses. However, in Items D.3, 2 and 3 of your application, it states that the mailing and location of use addresses are the same. Please clarify this discrepancy and explain which is correct.**

4. **A general observation and comment about your application, which used the checklist in NUREG 1556, Vol. 13, Rev. 1 ("the NUREG"): Many items, particularly in section D.5, items 5 and 6, the columns for materials to be**

possessed and proposed uses, were left blank. Either "yes" or "no" was supposed to be checked in the first two columns to indicate clearly which materials you were requesting.

5. Instead, you marked responses in some of the other columns, which lead to some confusion.

For example, the line item requesting materials in 10 CFR 31.11(a) is not marked "yes" or "no" but the quantity is filled in and in the final column "not applicable" contains marking." Please clarify whether you want authorization for this material or not.

The line item requesting depleted uranium shielding in not marked "yes" or "no" but the quantity is filled in and the last column is marked "shielding." Please specify how the depleted uranium will be used as "shielding" in the proposed pharmacy.

The line item requesting cesium-137 is not marked "yes" or "no", the uses written in the last column state "dose calibrator and well counter calibration."

This is incorrect. This item has "instrument calibration" preprinted on the form. It is intended for those pharmacies that will obtain sealed sources of cesium-137 in the hundred-plus millicurie range to calibrate their survey instruments with, and some also calibrate their clients survey instruments as a service, which is licensed through NUREG 1556, Vol. 18 for Service Providers.

In addition, no manufacturer's name or model number is filled in for the sealed source or the quantity. This is understandably incomplete because, although NRC now requires this information, it was not required during the last revision of this guide.

The line item on the form for materials authorized in 10 CFR 35.65 is intended for dose calibrator use and instrument checks, as stated in the preprinted section on the form.

However, we will need the manufacturer's names, radionuclides, activities and model numbers of the sealed sources you wish to possess – please provide this information.

Please also provide this same information for the cesium-137 if it is your intention to obtain this material to calibrate survey instruments.

6. As the proposed RSO, please submit a signed and currently dated statement stating that you accept the position as RSO and you understand the duties and responsibilities associated with that position.

7. If you really do not intend to obtain cesium-137 for use to calibrate survey instruments, or any other "non-ANP" uses, I can understand why you did not fill in Item 7.3, "Authorized Users."

However, it is always best to mark such items as "not applicable" to show that they were not overlooked.

But if you do intend to obtain cesium-137 to calibrate survey instruments, please provide the information requested in section 8.7.3 in NUREG 1556, Vol. 13, Rev. 1.

7. Your facilities and equipment information appears to be rather incomplete and difficult to decipher, especially since the handwriting is placed in several different directions on the diagram and details shown on the diagram are not very clear.

Please also describe the zoning for the area in which the pharmacy is located and identify all of the nearest structures. It appears that at least one house is located near the pharmacy, which is unusual for commercial radiopharmacies.

Please explain, briefly and concisely, what a "pressure controlled pass-through" is and what "pass-through boxes" are, where they are placed and how they will function.

Please resubmit the diagram in entirety, using additional 8.5 x 11 inch pages as necessary to clearly show each area in detail. Please include such details as whether each area/room is restricted or unrestricted (some areas were described as restricted or unrestricted but not all), the locations of all doors, pass-throughs, "hand-foot" monitoring stations, the locations and types and thicknesses of shielding to be used (including waste cans), and all of the information in item 9 in Appendix D, NUREG 1556, Vol. 13, Rev. 1, including air monitoring, glove boxes and ventilation system information to demonstrate that effluents will be ALARA. See the sample diagram shown in Figure 8.3 in the NUREG for assistance.

This last piece, information about air monitoring, glove boxes and ventilation system information was completely lacking in the application. Your application appeared to contradict itself with respect to iodine-131 possession and use.

In items 5 and 6 of your checklist and in item 9, it was stated that, for iodine-131 and iodine-123, that only capsules would be used, with no manipulation. It was also stated that xenon-133 would not be stored in this pharmacy either.

But your diagram shows a vacuum pump and air monitoring equipment and the table in your application listing maximum radionuclides in shielded transport containers and radiation levels at the surface of the containers includes listings of iodine-131 solutions in multi-millicurie quantities.

Please briefly and clearly explain these discrepancies and state explicitly what you intend to do with volatile materials such as iodine-131. Depending on this answer, we will have to determine whether appropriate air monitoring and ventilation system information must be provided, as well as bioassay commitments, etc., to demonstrate compliance with 10 CFR Part 20 and 10 CFR 30.33.

8. Items 8 and 8.2 describe your training program. Please refer to section 8.8.1, 8.8.2 and Appendix N in the NUREG for assistance in preparing your response.

Please note that I excluded from my review all of the RPS-provided Hazmat, DOT, etc. training, which consisted of about 64 pages, because it was voluminous and extraneous. I also excluded the sample bill of lading, the DOT Specification 7A Type A package design report and bar codes pages for the same reason.

Please see the sample response requested in section 8.8.2 and item10.9 on the checklist you submitted, in the NUREG.

Please kindly refrain from submitting such information in the future as it drastically slows down the review process and it is not requested or required during the licensing phase.

Your training program does not appear to include instructors, as none were mentioned. But slide shows, handouts and discussions are referred to. If there are no instructors, who are the discussions held with? Please identify who the instructors will be, by name and position and, if not already provided, describe their training and experience.

Please identify the groups of workers who will be included in this training program.

The sample examination submitted did not appear to address emergency procedures in its questions. Please confirm that this topic will be addressed in the written examination.

Please confirm that incorrect exam answers will be reviewed with each trainee to assure complete understanding of the material involved.

Please confirm that all references to "Mallinckrodt" will be replaced with "Lakeview Diagnostics, L.L.C.," for the sake of clarity when training your staff.

One document submitted in your training program is entitled "Nuclear Medicine Technologist Annual Instructions Regarding Radiation Safety and Operating Conditions." Please explain why the term "Nuclear Medicine Technologist (NMT)" is used in this document as it does not appear likely that you will be employing NMTs.

This same document also include references to "Quality Management Program" and "Regulatory Guide 10.8." Neither of these are current. Both were rendered obsolete in 2002 when revised 10 CFR Part 35 became effective. Please correct this document accordingly.

In item 8.2 it is stated that "Refresher DOT training and retesting occurs every 3 years." Please modify this commitment to also include that DOT training and retesting will occur whenever the DOT regulations and terms of the license change to warrant re-training.

9. Your sample label, at the bottom, indicates that the NRC "has approved the radiopharmaceutical.... for distribution pursuant to 35.14 and Group I of 10 CFR Part 35."

This is incorrect. "10 CFR Part 35.14" and "Group I" are obsolete references, as used in this statement. They became obsolete with the 1986 revision of 10 CFR Part 35. Please confirm that you will correct your labels.

Your application does not clearly and consistently describe shielding and labeling for vials, although it appears that vials will be dispensed. Please provide the appropriate commitments, explicitly, for vials, with respect to shielding, transport containers and labeling.

Please describe the colors you will be using for your labels.

On your product shielding table, please look at your Tl-201 values again. First an 8 mCi dose in a 1/8 inch shield for syringe results in 1.1 mR/hr dose rate. Then a 16 mCi dose in a 1/8 inch shield for a vial results in an 8.0 mR/hr dose rate.

This is the opposite of the values obtained for Ga-67, in which the vial resulted in a lower dose rate and for Tc-99m, in which the values were the same.

To ensure the table is correct, please advise us if the values for Tl-201 are, in fact, accurate, and if there is an explanation, please provide it.

10. Your application includes a request to add 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.

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 amendment of the license 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.

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

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.

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

11. To minimize exposures to persons handling and dispensing radioactive drugs, do you expect to utilize shielded pulley systems or similar devices, in addition to more traditional remote handling tools?

12. I am looking at the week of April 18, 2011, to make the site visit trip. I have other government business to conduct that same week, which is the earliest date available to me at this time, assuming, of course, that the government manages to avoid a "shutdown," due to lack of a budget.

Please let me know if that week may work out for you. I will be conducting a health and safety review, a pre-licensing security visit and we can discuss the items in this record, if you wish. We can also discuss these items via conference call prior to the visit, if you wish.

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 issue a new license 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 574220" and address it 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.

You may transmit your response to the fax no. above, 630-515-1078, and, if you do send a fax, please, at least leave a voicemail message for me, so I'll know to look for it, as it will be received in a processing area I do not ordinarily have access to. We will then continue our review.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	April 3, 2011

TRANSMISSION VERIFICATION REPORT

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SEND TO: DAVE SCHMITT, R.Ph.

LOCATION: Lakeview Diagnostic LLC

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

FROM:
(SENDER) COLLEEN CASEY

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

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MESSAGE

Dave, lets discuss this at your earliest