

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

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CONVERSATION RECORD

|TIME

|DATE

**ACTUALLY TRANSMITTED? YES.**

**December 12, 2010**

**Transmitted on 12/12/10 for site visit on 12/14/10**

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NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Benjamin L. Collins, R.Ph., proposed RSO for Hot Shots Nuclear Medicine

906-869-1759

Fax: 269-254-8577

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SUBJECT

License No.: PENDING

Control No.: Formerly 573604

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SUMMARY

We have reviewed your application dated September 2, 2010, your letter dated September 2, 2010, and your letter dated October 20, 2010, requesting a new byproduct materials license and find that we need additional information as follows:

1. **At this time, if your facility is completely built-out, and in order to reactivate processing of your new license, please send a currently signed and dated letter or fax to my attention at 630-515-1078 and reference the control number you had previously, 573604. Please provide a written response with the complete, correct mailing address, telephone numbers and fax number.**
2. **Your application requests authorization for up to 200 millicuries of cesium-137 sealed sources for instrument calibration. No calibration device is mentioned by manufacturer and model number, no person who will perform calibrations is designated, nor their training and experience, a description of where you will perform these calibrations and the procedures you will use, etc. This is all information we would need to begin consideration of your performing survey instrument calibrations internally for yourselves, as a service to others or both.**

**Since no information regarding instrument calibration is provided, and depending on your answer, we may need either a minimal amount of additional information or alot (see NUREG 1556, Vol. 18, as referenced in NUREG 1556, Vol. 13, Rev. 1, section 8.6.4.)**

**We can discuss this further during the site visit to better clarify what is meant here and what you intended.**

3. **Where do you stand with respect to obtaining your state of Michigan pharmacist's license, Mr. Collins? Please provide a timetable based upon your best "guesstimate."**

4. Where does Hot Shots Nuclear Medicine stand with respect to obtaining its state of Michigan license as a pharmacy? Please provide a timetable based upon your best "guesstimate."
5. In order to consider you, Mr. Collins, Eric Lester, R.Ph. and Daniel Trajchel, R.Ph. as Authorized Nuclear Pharmacists for this license (and for Mr. Collins, as RSO), please submit complete, signed and dated copies of the Agreement State licenses that list each of you as an ANP. Please note that excerpts of licenses are not acceptable. Please note that I do not have access to Agreement State licenses.
6. Mr. Collins, 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. I noted that NUREG 1556, Vol. 13, Rev.1, Appendix C responses on your application are filled in for Ra-226 sealed sources but the rest of your application is not filled in for Ra-226. Please clarify whether it is your intention to obtain Ra-226 or not and withdraw this if it was an error.
8. Please confirm that the letters you provide to the police and fire departments in your area will have appropriate telephone numbers on them to enable the civil authorities to reach the RSO, manager, or pharmacist on duty in an emergency.
9. Your application goes into quite a bit of detail about your air monitoring and sampling program for volatile iodine-131. However, I'm having difficulty understanding why you would only monitor and sample for I-131 seven days per month instead of continuously? Please explain and justify/support, as appropriate.
10. Please clarify and justify/support, why you will only conduct bioassays on persons who may be exposed to volatile I-131 on a monthly basis or within 24-36 hours of exposure? Why wouldn't you conduct bioassays on these persons within 24-36 hours of each exposure?
11. The sample for Label A is indecipherable – please resubmit a clearer copy, it may be necessary to enlarge it (?)
12. Please reconsider your decision to make the after-hours radioactive package dropoff area an "unrestricted area." As this area is secured for your couriers only, it appears to be a "restricted area," per the definitions of these terms in 10 CFR 20.1003. Please confirm that this area will be changed to a restricted area. (Attachment 5, Item 9.2)
13. 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?

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>.

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ACTION REQUIRED

Submit the requested information within 30 calendar days (by January 14, 2011) by referencing control number (573604) to facilitate proper handling. Note that, upon reactivation, this case will receive a new control number and you should use that number to respond instead of 573604. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address. 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. We will then continue our review.

If you cannot meet the requested response date please call me to arrange for an alternative date to respond. Please note that I expect to be on leave from ~ Dec. 17 - 26, 2010, but it is possible that that could change.

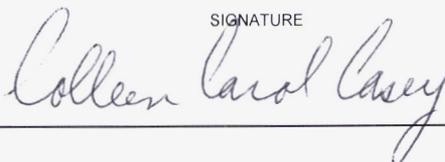
PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025, ext. 9841

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NAME OF PERSON DOCUMENTING CONVERSATION

Colleen Carol Casey

SIGNATURE



DATE

December 12, 2010

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