



UNITED STATES

NUCLEAR REGULATORY COMMISSION

REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

FEB 10 2011

Patrick M. O'Toole, M.D.  
Radiation Safety Officer  
St. Joseph Health Center  
1000 Carondelet Drive  
Kansas City, MO 64114

Dear Dr. O'Toole:

Enclosed is Amendment No. 57 to your NRC Material License No. 24-02704-01 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

**Please note that my deletion of your authorization for iodine-125 in the Proxima Therapeutics GliaSite RTS has resulted in the re-ordering of the Subitem numbers in 6 through 9 D.**

**In addition, the deletion of the Proxima Therapeutics GliaSite RTS authorization also resulted in the deletion of Drs. Hoskins, Lindstrom, Coster, Elman, Hart, Qamar and Keleti because this was the only material these authorized users were authorized for on your license.**

1. **In reviewing the letter dated November 15, 2010, which was the basis for your amendment request, it appears that the descriptive details of your facility diagrams for the cardiac PET program are incomplete.**

**In order to complete this amendment, please submit the information requested, addressed to my attention as "additional information to control number 573937," to facilitate proper handling in our office. We will then continue our review.**

**Please submit a written response that is currently signed and dated by a senior management official.**

**Please submit a revised diagram and description of your proposed cardiac PET facilities that includes the floor and room numbers in the hospital where these facilities will be located. Please include all of the information requested in NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program -**

**Specific Guidance About Medical Use Licenses,” in Section 8.15, Item 9 and Figure 8.1.**

2. Please note that I was unable to approve Corey W. Chopra, M.D. as an authorized user (AU) for materials in 10 CFR 35.100 and 35.200 at this time because the information in your letter dated November 15, 2010, was insufficient to complete my review.

If you wish to pursue this request, please submit the information requested below and address it to my attention as “additional information to control number 573937.” We will then continue our review.

I was unable to verify Dr. Chopra’s preceptor’s qualifications because the preceptor, Wendell Y. Yap, M.D. references the University of Kansas Medical Center (“UKMC”), an Agreement State license (that we do not have access to) that could also be a broad scope license, i.e., it does not name AU’s on its license document directly; rather, its Radiation Safety Committee evaluates and approves/disapproves of AU’s internally.

Please submit a copy of the Agreement State License for UKMC, and, if appropriate, please also submit a letter currently signed and dated by the Chair of the Radiation Safety Committee stating which modalities Dr. Yap was authorized for under the license and which timeframes he held said authorization.

Please do not submit copies of minutes from the licensee’s RSC meetings, email messages or other documents from the Agreement State licensee, especially patient records, or extraneous documentation that we must protect, per 10 CFR 2.390.

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

Please do not submit resumes, CV’s, 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.

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.”

3. Please note that, at this time, due to a change in NRC's licensing policies, we must obtain finite possession limits for all materials listed on your license except materials in 10 CFR 35.100 and 35.200.

This means that, for materials listed in Subitem No. 8.D. for 31.11, you must submit a possession limit. Your requested possession limit should factor in waste streams, may allow room for "reasonable growth" over time, and should be realistic for your needs. Most licensees request a possession limit of three millicuries for materials in 10 CFR 31.11. Please be reminded that you can always request an amendment to your license to adjust your possession limits as your needs change in the future.

Please respond to this request within 30 days of the date of this letter by submitting a written response to my attention, as "additional information to control number 573937" that is appropriately signed and dated.

If you will be unable to respond within this timeframe, please contact me at one of the telephone numbers below to arrange an alternative response date. Thank you in advance for your cooperation in this important matter concerning your NRC license.

4. This also refers to the telephone conversations on various dates, between Walter Kopecky and me and Dr. James Sear and me and the voicemail messages left for me by Marci West on February 8 and 9, 2011, concerning the cardiac PET program portion of your amendment. Unfortunately I was unable to return Ms. West's calls prior to issuing this amendment.

In order to give all of our licensees fair consideration in processing licensing correspondence, we normally review cases in chronological order based upon the date received.

What this usually means is that, as we advise you in our acknowledgment of receipt correspondence for casework, we will complete our initial review within 90 days of receipt for new license applications and amendment requests and within 180 days for license renewals.

So whenever possible, please submit your license amendment request at least 90 days before the date when you may need the new authorization to be effective. Please also be reminded that the technical review may result in the need for additional information that may or may not be able to be addressed within that initial 90 day window.

If that is not possible, it would be helpful for you to contact us by telephone immediately if an emergent and unforeseen medical situation arises after you have submitted an amendment request to your license.

**Please be prepared to specify the exact date when you will need the amendment and be able to briefly but specifically justify and support the need for that particular amendment.**

**Please note that "expedite, stat or as soon as possible" does not constitute a specific date. Please also note that we understand that virtually all licensing requests carry economic implications for all of our licensees.**

**You may also assist the licensing process greatly by preparing a high quality application containing an appropriate level of relevant detail, in accordance with the information described in NUREG 1556, Vol. 9, Rev. 2 or other guidance available on our website.**

**The exclusion of extraneous documents can also assist the licensing process and enable us to serve your needs more efficiently.**

**Please also ensure that an appropriate senior management official and/or your Radiation Safety Officer signs and dates the amendment request letter. Please include the name of a knowledgeable contact person who is familiar with your amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you.**

**We thank you in advance for your patience and cooperation in these matters.**

**If you have any questions or comments concerning this amendment please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078.**

In accordance with 10 Code of Federal Regulations 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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

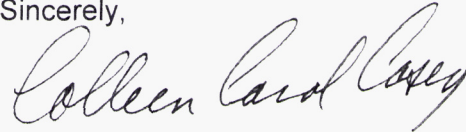
You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

P. O'Toole

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey  
Materials Licensing Branch

License No. 24-02704-01  
Docket No. 030-02310

Enclosure: Amendment No. 58