UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

DEC 0 9 2005

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. 54 renewing your NRC Material License No. 24-02704-01 in accordance with your request. Please note that some of the changes made to your license are printed in **bold** font. Your license has been issued for a ten year term and will not expire until December 31, 2015.

Please 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.

A. This also refers to the telephone conversation between Donna Stanton and me on December 9, 2005, concerning sections of your renewed license that are incomplete. It was agreed that you would provide the additional information required to complete your license within 30 days of the date of this letter. I am temporarily continuing your authorization in subitem Nos. 6., 7., 8., and 9. D. and E. Please address your response to my attention and reference control number 314546 to facilitate proper handling.

When my review of your response is final, I will amend your license to authorize the appropriate manufacturers, model number and corresponding radionuclides for the materials in 10 CFR 35.500 and 35.1000 that you wish to use, as well as the remaining changes needed to your license.

Please clarify and/or provide the following information to complete the renewal of your license:

1. Please provide the radionuclides, manufacturer's names and model numbers for all sealed sources you possess or intend to possess under 10 CFR 35.500. Please note that the information you provide to us must match up exactly with the manufacturer - provided data in the Sealed Source and Device Registry, which can be obtained from your vendors. I already consolidated your previous authorization for cesium-137 in the ADAC transmission device into your authorization for 10 CFR 35.500 materials and deleted former line item 6.G., as it appeared on Amendment no. 53.

   Please contact me at one of the telephone numbers below if you need assistance. You may also refer to NUREG 1556, Vol. 9, Final, Section 8.5, Item 5 and Table C.2, Items 5 and 6.

   In addition, please note that I retained your previous authorization for the use of materials in 10 CFR 35.400 because information necessary to delete this authorization was not provided in your renewal correspondence.

Further, Condition No. 13 was not addressed in your renewal correspondence. Please direct us to either retain or delete each of these authorizations from your license and provide appropriate supporting information to effect their deletion, as necessary.

If you wish to delete authorization for the use of materials in 10 CFR 35.400, then you must include a complete historical review of all actual licensed materials used that specifies when and where the materials were used and how, when and by whom were the materials disposed of (returned to holder of license number 24-19486-02, shipped off -site, decayed -in-storage, returned to vendor, etc.) A copy of the acknowledgment of receipt for the last sources used must also be submitted.

If any licensed materials under 10 CFR 35.400 were ever used under your license, please also submit final status survey information covering those radioactive materials. The final status survey should consist of the last leak test results for the sources used under this license. If that information is lacking, please contact me to discuss alternative information that can be provided.

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

2. In order to save time and effort, it is always best to prepare licensing correspondence in accordance with NUREG 1556, Vol. 9, Rev. 1, Final, especially Appendix C and Tables C.1, C.2 and C.3. In addition, guidance specific to the iodine-125 Iotrex GliaSite Therapy System and 10 CFR 35.1000 can be found on our website at:

http;//www.nrc.gov/materials/miau-reg-initiatives/liquid-brach.html

At this time I was unable to approve your request to add authorization for iodine-125 Iotrex in the GliaSite Therapy System because the information provided in your renewal correspondence was insufficient to complete my review.

Commitments we will require to complete this action can be found in the attached excerpt from this webpage. Please commit to, specifically confirm and/or describe those items noted in the attachment.

Please confirm that all other radiation safety program elements, currently authorized by your license for the use of materials in 10 CFR 35.400, will be followed for the use of the iodine-125 Iotrex in the GliaSite RTS system, **except** as specifically noted otherwise.

Please note that, although the SSDR certificate for the I-125 GliaSite does not require a leak test, NRC does require leak test - type evaluations of the GliaSite product and the maintenance of records thereof.

Until your license can be successfully amended to include iodine-125 Iotrex in the

GliaSite RTS system, I re-authorized the physicians requested for the iodine-125 Iotrex in the GliaSite RTS system, but instead I authorized them again for the use of materials in 10 CFR 35.400. Their authorizations can be added to or changed to authorization for materials in 10 CFR 35.1000, limited to iodine-125 Iotrex in the GliaSite RTS system at a later date then.

3. Please resubmit your facility diagrams and provide all of the appropriate information requested in NUREG 1556, Vol. 9, Rev.1, Section 8.15 Item 9, Facility Diagram, and Appendix C, Item 9, Facility Diagram, excerpts attached.

4. For the use of your dose calibrator, please confirm that "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

5. Since your renewal was not completely prepared in accordance with NUREG 1556, Vol.9, Rev. 1, I retained the previously approved documents in your "tie-down" condition, No. 14. When your response can be incorporated into your license I will delete the documents from Condition No. 14 that pre-date this renewal.

Full use of the NUREG 1556 Vol.9, Rev.1 document and the associated guidance for 10 CFR 35.1000 materials on our website would have greatly reduced your regulatory burden and enhanced safety by providing for more comprehensive, updated safety procedures and a complete renewal application.

Using the NUREG 1556 series documents will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner. In preparing your responses and all future licensing correspondence please focus on providing the information requested in Appendix C to NUREG 1556, Volume 9, Rev. 1.

Follow the"Suggested Format.." provided in Appendix C and use the suggested responses and model procedure/appendix references whenever possible, appending descriptive information as appropriate. It is advisable to read the corresponding text in the front of each NUREG to ensure a complete understanding of the commitments that you make.

Please do <u>not</u> submit resumes, curricula vitae, college transcripts, any personal, proprietary information, blueprint diagrams, and any extraneous, detailed information, procedures and retyped sections from advisory text in the NUREG-series documents.

It is also <u>not</u> necessary to resubmit training and experience information for incumbent staff and users named on the license, whose licensed functions are not changing. You may simply reference each appropriate person's position and name and state that his/her training and experience documents are already on

file in the license.

If you must deviate from a model procedure or suggested response, it may be possible to simply indicate what the deviation is and still use the model procedure/ suggested response as a "basic" commitment. Descriptive information may be "recycled" directly from previous documents only to the extent that it is current, complete information, equivalent to the model procedure (as appropriate) and does not contain extraneous material.

It is in your best interests to only provide those commitments, statements, representations and procedures, in a clear and explicit manner, that we require to issue your license. These documents will form the basis for the license in the last condition of the license, called the "tie-down" condition.

You will realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

In fact, the easiest way to prepare your licensing correspondence is to take a copy of NUREG 1556, Vol. 9 Rev. 1 to your copy machine and copy Appendix C section directly.

Read the text in the front of the NUREG that corresponds to each item in each Appendix C section and simply fill in the checkmarks and blanks on the copied checklists, thereby making your license commitments.

As noted above, please do not re-type the checklists as errors and omissions may be introduced. If you need to append certain information or provide an alternative procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness.

Also, please check your current license to ensure that you have not omitted anything that you wish to continue authorization for, such as locations of use, line items, etc. On the other hand, if you wish to delete an authorization that you currently have, be sure to specifically request the deletion, state why, and support each request with appropriate information that justifies granting the request (such as leak tests, final surveys, acknowledgments of receipt from vendors, etc.)

B. Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection

Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days, pursuant to 10 CFR 35.14:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license changes.

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers, except as provided in 10 CFR 35.24©);

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or the address or addresses of use identified in the license application or on the license, pursuant to 10 CFR 35.13(e), 10 CFR 35.13(f) and 10 CFR 35.14(b)(4); or

   d. Change ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for an application for medical use must be the licensee's management, as required by 10 CFR 35.12(a).

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).

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. 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,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

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

Enclosures:

1. Amendment No. 53
2. NRC website excerpt for
   10 CFR 35.1000GliaSite guidance
3. NUREG 1556, Vol. 9, Rev.1
   excerpt for facility diagrams