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

MAY 2 6 2012

Sam S. Hancock, Ph.D.
Radiation Safety Officer
Southeast Missouri Hospital
1701 Lacey Street
Cape Girardeau, MO 63701

Dear Dr. Hancock:

We have reviewed your application dated October 25, 2010, requesting renewal of your byproduct materials license and, incidentally, your letters dated March 9, 2011, and April 17, 2011. We find that we need additional information as follows:

1. **Your application was silent with respect to continuing authorization for incumbent Authorized User (AU) Bryan S. Beck, M.D. He has been authorized for the use of materials in 10 CFR 35.200. We checked your amendment requests for the past three years and have not found a request for Dr. Beck's removal from your license.**

   As an interim measure, we have continued Dr. Beck's authorization.

   Please explicitly advise us as to whether Dr. Beck should continue as an AU under your license.

2. **Your application requested continuation of Mark L. Pfautsch, D.O.'s authorization as an AU only for the use of material in 10 CFR 35.200.**

   However, he is currently an AU for the use of materials in 10 CFR 35.100, 35.200, 35.300 and 35.500.

   Please explicitly advise us as to what Dr. Pfautsch should remain an AU for under your license and specifically request how his authorization should be changed, if that is appropriate.

3. **Please note that there have been several name changes among the manufacturers and distributors of the sealed sources authorized on your license for 10 CFR 35.400 and 35.500. These name changes also differ from those requested in your application, in some cases.**

These name changes reflect the current names for these companies in our records and the changes will appear on your renewed license in bold font. This is for your information only and no response is required.

4. **However, one name change in your application could not be effected at all. It was for the GliaSite iodine-125 Iotrex radiation therapy system (RTS) under the "Hologic" name. Our records show this product is still under the "Cytyc" corporate name so we had to continue that in Subitem Nos. 6 through 9 G, inclusive. This should have no effect on your ability to use the product and no response is required.**

5. **For the continuation of your GliaSite RTS authorization, currently in Subitem Nos. 6 through 9 G., into the renewed license, please provide written responses and commitments, based upon the guidance found on our website at:**

   http://www.nrc.gov/materials/miau/med-use-toolkit/liquid-brach.html

   This information appeared to have been either incompletely addressed or missing from your application.

   a. **Please confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where other commitments and conditions in your license provide relief.**

   b. **For brachytherapy using Proxima Therapeutics' GliaSite® RTS, please confirm that "prescribed dose" means the total dose documented in the written directive.**

   c. **The written directive should include (1) before implantation: the treatment site, the radionuclide (including the chemical/physical form [Iotrex™]), and dose; and (2) after implantation but before completion of the procedure: the radionuclide (including the chemical /physical form [Iotrex™]), treatment site, and the total dose.**

   d. **Please confirm that you will provide instructions on how to safely handle contamination of unsealed materials, in addition to the instructions required by 10 CFR 35.410, "Safety instructions."**

   e. **Please confirm that "Source leakage" for the Iotrex™ implanted in the GliaSite® RTS means leakage of I-125 that results in a dose that exceeds 0.5 Sv (50 rem) dose equivalent to any individual organ other than the treatment site (based on definition of a medical event).**

f. **Please confirm that you will retain a record of the leak test for three years (the period that 10 CFR 35.2067 requires for brachytherapy sources).**

g. **Please confirm that you will report a leaking source to the NRC within five days of the leakage test to the locations specified and provide the information identified in 10 CFR 35.3067.**

h. **Section 10.2 of your application, "GliaSite Safety Procedures and Instructions," states, under "Provision for leakage on page 44, paragraph one, that "If the dose to the critical organ exceeds 50 rem, the event will be handled and reported as a misadministration."**

Please be reminded that "misadministration" ceased being an NRC-defined term in April 2002 when 10 CFR Part 35 was completely revised. 10 CFR 35.2 now defines "medical events." In response, please state that the term "misadministration" will be replaced by the term "medical event."

i. **The following is excerpted from our website (at the link given above) and is for your information only, if you wish to incorporate this into your license at this time, or in the future. Please note that an explicit request following the information requested/formatted below should be submitted.**

"Revision of the Cytyc Surgical Products' GliaSite® Radiotherapy System radiation safety programs to conform to changes in this licensing guidance.

(1) The above-licensing guidance may be revised as additional experience is gained regarding the medical use of Cytyc Surgical Products' GliaSite® RTS. A licensee already authorized to use this product that is committed by license condition to follow provisions in this guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform with the revised provisions.

(2) An applicant initially applying for authorization for the medical use of Cytyc Surgical Products' GliaSite® RTS, or a licensee applying for an amendment to conform with revisions in this guidance, may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

(3) (a) the revision is in compliance with the regulations;
(b) the revision is based upon NRC's current guidance for Cytyc Surgical Products' GliaSite® RTS 35.1000 use postes on the NRC Web site;
(c) the revision has been reviewed and approved by the

licensee's radiation safety officer and licensee's management;
(d) the affected individuals are instructed on the revised program before the change is implemented;
(e) the licensee will retain a record of each change for five years; and
(f) the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

(4) If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license."

6. **In accordance with section 8.20, Item 9, in NUREG 1556 Vol. 9, Rev. 2, please describe your emergency response equipment for the use of manual brachytherapy materials. Such equipment may include, but need not be limited to, remote handling tools, portable shields, wire cutters, etc.**

7. **We also incidentally reviewed your letters dated March 9, 2011, and April 17, 2011. In the letter dated March 9, 2011, you requested a 50 millicurie gadolinium-153 sealed source for the Siemens Symbia-S gamma camera system.**

   In the letter dated April 17, 2011, you withdrew the request, stating that it appeared this source was included in 10 CFR 35.65.

   In the scope of our current review, it appears that the requested source cannot be included in 10 CFR 35.65 because it exceeds the 30 millicurie limitation.

   This appears to be a misunderstanding.

   Please advise us if you wish to add this source to your license at this time.

Please submit a written response to the above information, where responses are requested, within 30 days of the date of this letter, or sooner, if you prefer. If an alternative response time is needed please contact me to make arrangements.

When preparing this information please address it to my attention at the address above as "additional information to control number 573785" to facilitate proper handling in our offices.

This is a different control number than you may have been previously directed to you. This control number uniquely identifies the renewal application for your license.

If you have any questions or require clarification on any of the information stated above, you may contact me directly at (630) 829-9841 or you may reach our administrative support staff at (630) 829-9887. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

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.

The NRC's Safety Culture Policy Statement became effective in June 2011.

While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at:

http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 24-00128-01
Docket No. 030-02264