## Casey, Colleen

**From:** Sam Hancock [shancock@sehealth.org]
**Sent:** Friday, June 22, 2012 3:58 PM
**To:** Casey, Colleen
**Cc:** Sly Moore; Judy Aslin; Barbara Bucher
**Subject:** Response for Control Number 573785
**Attachments:** Response to letter dated 052612.pdf; ATT00001.txt

Colleen,
Attached is my response to your letter dated 5/26/12 regarding our renewal application.

Best Regards

**Sam S. Hancock, PhD**
***Chief Physicist & Radiation Safety Officer***
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June 22, 2012

U.S. Nuclear Regulatory Commission
Region III, Material Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

via email: Colleen.Casey@nrc.gov

Att: Colleen Casey

Dear Ms. Casey,

Re: Control Number 573785; License No. 24-00128-03

This is in response to your questions regarding our pending renewal request as listed in your letter dated May 26, 2012. The item numbers below correspond with those in your letter.

1. Please continue Dr. Bryan S. Beck's authorization.
2. Please continue Dr. Mark L. Pfautsch's authorization for uses in 10 CFR 35.100, 35.200, 35.300, and 35.500.
3. The name changes of manufacturers and distributors of sealed sources is duly noted. However, at this time we have made the decision to discontinue the permanent seed implant service. Accordingly, we request the removal of authorization for sealed sources of Pd-103, I-125, and Cs-131 in Subitem 6D and 9D for uses permitted by 10 CFR 35.400. The removal of this authorization leaves only the strontium-90 sealed source, in DuPont Merck Parmaceutical Co. Model NB-1 Eye Therapy Applicator, for uses permitted by 10 CFR 35.400.
4. The manufacturer's name for the GliaSite iodine-125 Iotrex® RTS is duly noted.
5. With regard to our use of the GliaSite RTS:
   a. We 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 our license provide relief.
   b. "Prescribed dose," for brachytherapy using GliaSite RTS, means the total dose documented in the written directive.
   c. The written directive will include
      1) before implantation: the treatment site, the radionuclide (including the chemical/physical form [Iotrex®], and dose;
      2) after implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Iotrex®], treatment site, and the total dose.
   d. We 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. "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. We will retain a record of the leak test for three years (the period that 10 CFR 35.2067 requires for brachytherapy sources).
g. We 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. Provision for leakage: We will evaluate all events which occur involving the unexpected loss of retained radioactivity in the catheter and assess the dose to the critical organ (bladder wall, per Iotrex® Package Insert). If the dose to the critical organ exceeds 50 rem, the event will be handled and reported as a medical event.
i. We request authorization to make future changes to our radiation safety program with respect to the use of GliaSite iodine-125 Iotrex® RTS, provided the following conditions are met:
   1) the revision is in compliance with the regulations;
   2) the revision is based upon NRC's current guidance for Cytyc Surgical Products' GliaSite RTS 35.1000 use posted on the NRC Web site;
   3) the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management;
   4) the affected individuals are instructed on the revised program before the change is implemented;
   5) the licensee will retain a record of each change for five years; and
   6) 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.

6. Other equipment and facilities:
   The strontium-90 eye applicator is stored in the shielded transport container provided by the manufacturer. This strontium-90 source has a long handle which includes a circular transparent plastic plate to shield the hand during use. Long-handled forceps are used for performance of leak test wipes.
7. Although we had requested, in my letter dated March 9, 2011, a maximum amount of Gd-153 of 50 millicuries, the Eckert & Ziegler Model HEGL-0133 sealed source has an activity of only 10 millicuries each. Since 10 CFR 35.65 allows sources with activity up to 30 millicuries, this source does not need to be added to our license.

If you have any further questions regarding this matter, feel free to contact me at 573-519-4710 (office) or 573-270-7492 (mobile).

Sam S. Hancock, PhD
Radiation Safety Officer

cc: Sylvia Moore, VP, COO
Judy Aslin, VP, CNO