December 13, 2002

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA, WISCONSIN

10 CFR PART 32 - INTERPRETATION - SEALED SOURCE OR DEVICE CERTIFICATION (STP-02 - 082)

The U.S. Nuclear Regulatory Commission (NRC) has made a determination that a medical product, used for administering I-125 seeds for brachytherapy, does not require registration as a sealed source or device (SSD). The enclosed letter to an NRC licensee is being provided for your information and to promote consistency in regulatory approach used nationwide. Although this letter addresses a specific product, it essentially establishes NRC's position on SSD certification for brachytherapy seeds placed in strands.

Background

On July 31, 2002, Advance Care Pharmacy, located in Woodbury, Connecticut asked the NRC staff for clarification on whether its Readi-Strand product needed to be registered as a sealed source or device. The Readi-Strand is used in brachytherapy; it consists of commercially available and registered I-125 seeds molded into a bio-absorbable suture material. On November 22, 2002, the NRC staff determined that I-125 seeds, and not the Readi-Strand, are the products that needs registration in accordance with the provisions of 10 CFR 32.74. This determination is based on the presumption that the Readi-Strand constitutes a package for the administration and transportation of the seeds; that no changes have been made to the seeds which are to be supplied by the seed manufacturers as registered products; that the vendor will provide safety instructions for use; and that Advanced Care Pharmacy the vendor and the users will maintain a shelf-life which is sufficiently short to assure that the bio-absorbable material will retain its physical properties, strength, and flexibility until use.

If you have any questions regarding this correspondence, please contact me at (301) 415-2325 or the individual named below.

POINT OF CONTACT: Lloyd A. Bolling INTERNET: LAB@NRC.GOV
TELEPHONE: (301) 415-2327 FAX: (301) 415-3502

/RA/

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

STP-02-082

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OFFICE	STP		STP:DD							
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DATE	12/12/02		12/13/02							

November 26, 2002

Mr. Rick Terwilliger
Vice President/Technical Director
Advanced Care Pharmacy, LLC
125 Main Street North
P.O. Box 743
Woodbury, CT 06798

Dear Mr. Terwilliger:

This is a response to your letter (received on July 31, 2002, NRC file access No. ML022130046) requesting information on the registration of your Readi-Strand product as a sealed source device. Based on your letter and on the additional information that you have provided in your letter dated August 15, 2002, and telefax on September 5, 2002, we understand that the Readi-Strand will be fabricated using commercially available, registered radionuclide seeds; the seeds will be molded into a bio-absorbable suture material; and that you will market the product for use in brachytherapy. You requested a determination whether the Readi-Strand needs to be registered for commercial distribution in accordance with the provisions of 10 CFR 32.74.

We have reviewed the information that you provided in terms of the regulatory requirements, the approval of your product by the Food and Drug Administration, as well as the registration of iodine-125 seeds by the NRC and the Agreement States. Based on this review, we have determined that the iodine-125 seeds and not the Readi-Strand are the product that needs registration in accordance with the provisions of 10 CFR 32.74. In order to distribute the iodine-125 seeds in your Readi-Strand product to NRC licensees for use under 10 CFR 34.400, Advanced Care Pharmacy will need to obtain a medical distribution license from NRC Region I office in accordance with 10 CFR 32.74.

The conditions for this determination presume that the Readi-Strand constitutes a package for the administration and transportation of the seeds; that no changes have been made to the seeds which are to be supplied by the seed manufacturers as registered products; that Advanced Care Pharmacy will provide safety instructions for use; and that Advanced Care Pharmacy and the users will maintain a shelf-life which is sufficiently short to assure that the bio-absorbable material will retain its physical properties, strength, and flexibility until use. If any of these presumptions is incorrect, please notify us for further consideration of your request.

If you have further questions, you may contact Thomas Essig, of my staff, at (301) 415-7231, or through e-mail, at the@nrc.gov.

Sincerely,

/RA/ SMFrant for
Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards