

March 1, 2007

Mr. Jesse Funches
U.S. Nuclear Regulatory Commission
Chief Financial Officer
Washington, DC 20555

Re: SSDR Fee Exemption

Dear Mr. Funches:

Advanced Care Medical has prepared a SSDR Application, as requested by the NRC in response to a request made by James P. Dwyer, Chief Commercial and R&D Branch Division of Nuclear Materials Safety. The request was made June 6, 2005 (EA 05-013, Docket 03036099, 03036179).

We are requesting that the application fee be waived in accordance with CFR 170.11 Exemptions, (ii) in response to an NRC request to resolve an identified safety issue.

Since September 2004, when a perceived safety issue was identified, Advanced Care Medical has provided the NRC with a full description of our processes, forms, standard operating procedures and an independent risk analysis of all operations.

After receiving the June 6, 2005 request, we provided the NRC with a list of eleven (11) other "brachytherapy sealed source strand providers". The NRC has investigated these manufacturers and confirmed their 2002 decision that "*a medical product (stranded) used for administering seeds for brachytherapy, does not require registration as a sealed source or device*".

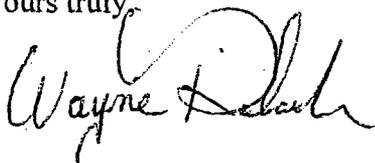
- * 11-26-02 Letter Donald A Cool, NRC Director / Rick Terwilliger, ACM Vice President
- * 12-13-02 10CFR Part 32-Interpretation -Sealed Source or Device Certification (STP-02-082)
Josephine M. Piccone, Deputy Director Office of State & Tribal Programs

There have been no identified "safety issues" with Advanced Care Medical stranded product since 2004 and over 10000 cases have been provided.

Advanced Care Medical maintains both possession and distribution licenses with NRC Region 1 and qualifies as a Small Entity for licensing purposes. I have been advised by the fee office that Small Entity Fees do not apply for Applications and the \$5600 SSDR application fee which applied in 2004 is now \$20900 in 2007.

We have addressed a perceived safety issue, identified by the NRC and would like to provide a confirmatory letter, indicating that the fee has been waived, with our application.

Yours truly,



Wayne Richardson
Radiation Safety Officer
Advanced Care Medical
115 Hurley Road
Oxford, CT 06478

203 262 4190 X105 wayne @wwmedtech.com

(STP-02-082, December 2002, Other, Device Certification, 10 CFR 32)

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 Read-Strand product needed to be registered as a sealed source or device. The Read-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 Read-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 Read-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
TELEPHONE: (301) 415-2327

INTERNET: LAB@NRC.GOV
FAX: (301) 415-3502

IRA/

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

Enclosure:
As stated

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 Read-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 Read-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 Read-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 Read-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 Read-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 Read-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