



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 19, 2005

Docket Nos. 03036099
03036179

License No. 06-30764-01
06-30764-02MD

Control Nos. 136464
136465

CAL No. 1-04-007

Gary Lamoureux
President / Chief Executive Officer
Advanced Care Medical
115 Hurley Road, Building #3A
Oxford, CT 06478

SUBJECT: ADVANCED CARE MEDICAL, CLOSURE OF CONFIRMATORY ACTION
LETTER NO. 1-04-007 AND ISSUANCE OF LICENSE AMENDMENTS,
CONTROL NOS. 136464 AND 136465

Dear Mr. Lamoureux:

This refers to your letter received September 7, 2004, and your letter dated November 3, 2004, submitted in response to our Confirmatory Action Letter (CAL) No. 1-04-007 dated August 26, 2004, and revisions to the CAL dated September 29, 2004, and November 2, 2004. This also refers to your February 9, 2005, request for amendment of your possession and distribution licenses.

The CAL dated August 26, 2004, described your agreement to provide NRC with: (1) your technical basis for permitting the heating of the sealed sources (iodine-125 seeds) to a temperature which exceeds the intended limitations indicated in the Sealed Source & Device Registry; and (2) a complete description of your process for incorporating the sealed sources into a strand and the basis used to determine each process would not modify the sealed sources as indicated in your September 5, 2002 letter. In your response received September 7, 2004, you indicated that the iodine-125 seeds complied with ISO 2919-199E and that this standard required the seeds to withstand temperatures significantly higher than the limit specified in the Sealed Source & Device Registry. Your response also provided a description of your process for incorporating the iodine-125 seeds into a strand; however, an inspection performed on September 13, 2004, identified strand cutting and sizing operations that were not delineated in the description you provided. In addition, we learned during the inspection that there had been approximately 10 instances when iodine-125 seeds were crushed or damaged during the seed stranding process. Accordingly, you agreed to provide additional information and to take additional precautions as described in the September 29, 2004, revision of the CAL.

The September 29, 2004, revision of the CAL described your agreement to provide, by October 22, 2004, detailed descriptions of the Read-Strand product, the strand construction process, any manipulation that you perform on the strands, the environmental conditions during processing, and quality assurance and quality control measures that are applied to the process. Furthermore, you agreed to leak test each source strand following completion of fabrication, including any strand cutting and sizing, prior to distribution, and to inform NRC of any leakage above background levels. In response to your request dated October 20, 2004, the CAL was revised again on November 2, 2004, to extend the agreed upon response date to November 5, 2004.

Your November 3, 2004, response to the CAL provided the agreed upon information and confirmation that each sealed source strand was being leak tested prior to distribution. The information you provided was reviewed by NRC staff and, on December 15, 2004, staff from the NRC Regional Office and NRC Headquarters Office visited your facility to view your process first hand. The staff from NRC Headquarters are currently reviewing the information you provided and the information they gathered during the site visit to decide if a formal Sealed Source & Device review of your Read-Strand product is required. You will be advised of this determination in future correspondence.

On February 9, 2005, you requested amendment of your possession and distribution licenses to incorporate your commitment, as described in the CAL, to perform contamination detection tests as part of your standard operating procedures. Accordingly, we have determined that you have completed all of the commitments described in CAL 1-04-007, and the two revisions of the CAL, and no further response to the CAL is required.

Thank you for informing us of the actions documented in your letters. These actions will be examined during a future inspection of your licensed program. Your cooperation with us is appreciated.

Sincerely,

Original signed by George Pangburn

George Pangburn, Director
Division of Nuclear Materials Safety

Enclosures:

License No. 06-30764-01, Amendment No. 7
License No. 06-30764-02MD, Amendment No. 7

cc:

Wayne W. Richardson, Radiation Safety Officer
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State of New York (without enclosures)
State of Oklahoma (without enclosures)
L. McLean, RIV (without enclosures)

G. Lamoureux
Advanced Care Medical

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