



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

September 23, 2005

Docket No. 03002466
Control No. 137248

License No. 29-03089-01

Michael Medina
Assistant Vice President
Somerset Medical Center
110 Rehill Avenue
Somerville, NJ 08876

**SUBJECT: SOMERSET MEDICAL CENTER, REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE,
CONTROL NO. 137248**

Dear Mr. Medina:

This is in reference to your application dated June 30, 2005 requesting to renew Nuclear Regulatory Commission License No. 29-03089-01. In order to continue our review, we need the following additional information:

1. In Items 5 & 6 of your application, you requested authorization for two different Iodine 125 (I-125) brachytherapy sources permitted by 10 CFR 35.400, with a possession limit of 1000 millicuries for each source. Your current license authorizes a possession limit of 200 millicuries for byproduct material permitted by 10 CFR 35.400. Please confirm that you would like to increase your total possession limit requested for byproduct material permitted by 10 CFR 35.400 to 2000 millicuries (2 curies).
2. In Items 5 & 6 of your application, you requested authorization for storage only of Gadolinium 153 (Gd-153) sealed sources (Isotope Product Laboratories, Inc. Model No. 3409). Please note that Gd-153 has a physical half-life greater than 120 days and cannot be held for decay-in-storage. You must actively pursue disposal of this material if you do not plan to use it in the future. Please describe your plan for future use or disposal of the Gd-153 sealed source(s) in storage.
3. In Items 5 & 6 of your application, you requested authorization for use of Proxima Therapeutics Gliasite I-125 solution for brachytherapy treatment. Please confirm that the commitments in the letters dated April 18, 2005 and July 18, 2005 regarding Gliasite authorization are applicable to the renewal of your license.
4. The documentation submitted for two proposed authorized users (AUs), Dr. Alan Saunders and Dr. Jeannete Greer, did not show specific clinical nuclear medicine training and experience obtained within the seven years preceding the date of your application. Please provide documentation of specific recent (within the past seven years) clinical nuclear medicine training and experience for Dr. Saunders and Dr. Greer. This documentation may include written statements by AUs describing each proposed users' recent clinical nuclear medicine training and experience.

5. Your application did not contain facility diagrams. For types of uses permitted by 10 CFR 35.100 and 35.200, please provide room numbers and diagrams for areas in which byproduct materials are used or prepared for use (i.e., "hot labs", dedicated injection areas, and scanning rooms). Describe adjacent areas and rooms (e.g., office, file, restroom, closet, hallway), including those above and below. For types of uses permitted by 10 CFR 35.300 and 35.400, provide the above information and the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under 10 CFR 35.75, including a description of any shielding. For types of uses permitted by 10 CFR 35.500, provide the room numbers of use. The facility diagrams should be to scale and the scale should be indicated on the diagrams.
6. In Item 9 of your application, you listed your survey instrumentation, including 2 GM meters and 1 ionization detection meter. Please describe the instrumentation that you use to detect dislodged I-125 brachytherapy sources. If you do not use a thin crystal sodium iodide detector, provide the detection efficiency for the type of detector used.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material**; then **toolkit index page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 137248. If you have any technical questions regarding this deficiency letter, please call Donna Janda at (610) 337-5371.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Vincent Immerso, M.S., Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML052700461.wpd

SISP Review Complete: DMJ

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	DJanda/DMJ		SGabriel/SLG					
DATE	9/23/2005		9/23/05					

OFFICIAL RECORD COPY