

January 19, 2005

Penny Lanzisera
Acting Branch Chief
Licensing Assistance Section
Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

License No. 06-00200-03

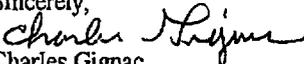
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Ms. Lanzisera

The Hospital of Saint Raphael in New Haven, Connecticut recently renewed its NRC License (Amendment 70). The Oncura Division of GE Healthcare, who is a vendor of I-125 sealed sources for brachytherapy, requested and received a copy of the renewed license yesterday (1/18/05) (the Hospital has been using this vendor as the supplier of I-125 brachytherapy sources since 1997). The vendor informed us today that they would not be able to ship two pending seed orders until our license specifically listed the model number of their I-125 source. They stated that the NRC had informed them of this requirement 6-8 months ago. Until they received a copy of our renewed license, they were not aware that the license did not have the specific model number listed. The two seed orders in question are to be used for two patients scheduled for implants next Wednesday (1/26/05). In order to be able to receive the seeds for the implants, they must be ordered by noon tomorrow (1/20/04). The seeds are shipped on Friday and received on Monday in order to allow assay and needle loading prior to the implants.

Earlier today, in an effort to resolve this issue, I spoke with Michelle Beardsley, who was the NRC reviewer for our license renewal. She stated that GE Healthcare was correct in requiring the specific listing of the seed model number, and pointed out that this information should have been itemized in the license renewal application. She suggested that I contact you in an effort to obtain an urgent amendment to our license for approval to use the Oncura Model 6711 (Oncoseed) and Model 7000 (Rapid Strand) I-125 sources. The sources are listed on the Registry of Radioactive Sealed Sources and Devices. Hopefully, you would be able to grant this approval today and fax a copy of the approval to the Hospital. The fax number for the Radiation Therapy Department is (203) 789-3133. If this approval was not received by tomorrow morning, we would be forced to postpone the patients' implants for two weeks. Since the patients have undergone fairly extensive medical workups in preparation for the implants, the authorized user has requested that I seek emergency approval from the NRC to allow the procedures to be performed as scheduled.

It is acknowledged that the specific source information should have been listed on the license application. With the best interests and welfare of the patients in question in mind, we ask for your assistance in resolving this matter. Thanks you in advance for your help

Sincerely,

Charles Gignac
Senior Physicist/RSO
Radiation Therapy Department
Hospital of Saint Raphael
1450 Chapel Street
New Haven, CT 06511

Telephone: (203) 789-3292 (Office)
(203) 789-3131 (Main Departmental Number)

Fax: (203) 789-3133

136307

NMSS/RGNI MATERIALS-002

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 02230
: Status Code: 0
: Fee Category: 7C 2B
: Exp. Date: 20141231
: Fee Comments: _____
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: HOSPITAL OF ST. RAPHAEL
Received Date: 20050119
Docket No: 3001238
Control No.: 136307
License No.: 06-00200-03
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed M. A. Perkins
Date 1/19/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /___/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____