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UNIVERSITY  
HOSPITAL



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REGION 1

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May 24, 2005

Ms. Sandra Gabriel  
Senior Health Physicist  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

SUBJECT: District Hospital Partners, L.P.  
D/B/A The George Washington University Hospital  
Request for Amendment to Special Nuclear Material License

REFERENCE: NRC License No. SNM-2007  
Docket No. 070-07006  
Reference No. SNM – 1499

Dear Ms. Gabriel:

We wish to apply for an amendment to our special nuclear material license. We are requesting to reduce our possession limit of special nuclear material to reflect two pacemakers, i.e., 250 milligram of Pu-238 per source and 0.50 gram total.

In response to your letter mentioning a potential discrepancy of the number of pacemakers in our possession, dated April 19, 2005, our records show that we have been following one patient with two implanted Coratomic C-101 pacemakers (serial numbers 1001 and 1061) since 1981.

The confusion apparently arose in 1993 when the then current RSO made a license renewal requesting three pacemakers with an equivalent amount of possession limit. The RSO anticipated that the Hospital might need or use a third pacemaker in the future.

We believe that the RSO made the request in order to have some flexibility in the cardiac pacemaker program. The plan was to have a pacemaker that could be removed or replaced as needed in an emergency situation without going over the possession limit. A letter from the RSO of the George Washington University is attached.

Ms. Sandra Gabriel  
May 24, 2005 – Page 2

We apologize for any confusion. There is no discrepancy in the number of pacemakers in our possession. We have two units. They were implanted in the patient. The request for a third unit was made only in the event that we might need one.

If you have any questions, please contact Anisuzzaman Chowdhury, Ph.D. at 202-715-4959 or pager 1-877-475-8994.

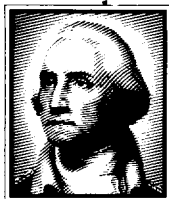
Sincerely,

A handwritten signature in black ink, appearing to read 'Richard Davis', with a stylized flourish at the end.

Richard Davis  
Chief Financial Officer

RD:na

cc: Anisuzzaman Chowdhury, Ph.D.



THE GEORGE  
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MEDICAL CENTER  
WASHINGTON DC

OFFICE OF RADIATION SAFETY

May 16, 2005

Anisuzzaman Chowdhury, Ph. D.  
Radiation Safety Officer  
The George Washington University Hospital  
c/o Office of Administration, Suite G-2054  
900 23rd Street, N.W.  
Washington, DC 20037

Dr. Chowdhury:

I have received your FAX of a copy of the letter dated April 19, 2005, to Richard Davis, GWU Hospital Chief Financial Officer, from Sandra Gabriel, U.S. Nuclear Regulatory Commission, Region I, Division of Nuclear Materials Safety.

Ms. Gabriel observed, "Your amendment request stated that you are currently following one patient with two pacemakers. We noted that your license renewal request in 1993 was for 'up to three' pacemakers .... Please resolve this discrepancy ...."

This license renewal request was a two-page letter dated March 19, 1993, to the NRC from the Office of the Vice President for Medical Affairs and Executive Dean of The George Washington University. I signed the letter, since I was the Radiation Safety Officer named on our NRC pacemaker license, and since I had drafted the letter with the consultation and approval of the two Department of Cardiology Division Directors who were responsible for cardiac pacemaker patient care, who each signed the letter. The final signatory was Allan B. Weingold, M.D., the Interim Vice President for Medical Affairs and Executive Dean.

The letter format used for this license renewal request was chosen to simplify the request, and to continue the special nuclear material (SNM) cardiac pacemaker program with very clear conditions, and with sufficient program flexibility.

As you know, we had only two SNM pacemakers at that time, which were both implanted in a single patient who lived in Virginia. We had not possessed any other SNM pacemaker, or had any interest in or responsibility for one, for many years prior to March, 1993; and have not since. However, I believe in possession limits that provide the Hospital some flexibility.

May 16, 2005

Anisuzzaman Chowdhury, Ph.D.

page 2

A patient might need to have a pacemaker removed or replaced unexpectedly while in our care, an Emergency Room patient, for example. This might be done soon after RSO arrival, before the RSO's arrival, or even before RSO notification. The device might be removed and then recognized as radioactive later. The NRC would be notified after explantation.

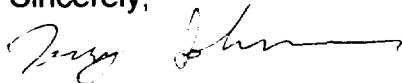
The RSO would immediately inspect the pacemaker and secure it safely, and would notify the NRC and the manufacturer promptly, after evaluating contamination samples from the pacemaker, the surgery room, equipment, etc., and the patient urine or serum, if warranted.

It would be best if the pacemaker were within our NRC license limits, so it could be stored in our facility, in tight security, pending shipment to the manufacturer or elsewhere as required.

Also, a pacemaker might be transferred from one NRC license to another, when a patient moves from one area to another or from the care of one licensed medical facility to another.

I hope this letter clarifies the possession limit issue. Please keep me informed of any additional correspondence concerning this matter. I can best be reached at 202-994-3149.

Sincerely,



Terry Johnson, CHP  
Director, Office of Radiation Safety  
The George Washington University  
2300 'I' Street, N.W.; Suite 617/627  
Washington, DC 20037

cc: Astra Bain-Dowell  
Katherine Kennedy, Ph.D.  
Glenda Hall

This is to acknowledge the receipt of your letter/application dated

5/24/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment SKM-2007/07007006  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 137105.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

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:      (FOR LFMS USE)
:      INFORMATION FROM LTS
:      -----
:
:  Program Code: 22160
:  Status Code: 0
:  Fee Category: EX 7C
:  Exp. Date: 20101130
:  Fee Comments: PACEMAKER/08-30607-01
:  Decom Fin Assur Req'd: N
:
: .....
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### A. REGION

1. APPLICATION ATTACHED  
Applicant/Licensee: DISTRICT HOSPITAL PARTNERS, L.P.  
Received Date: 20050526  
Docket No: 7007006  
Control No.: 137105  
License No.: SNM-2007  
Action Type: Amendment

- Amount: \_\_\_\_\_  
Check No.: \_\_\_\_\_

- ### 3. COMMENTS

Signed  
Date

Revised June 2012

- 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