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

January 14, 2005

Docket No. 03014754 License No. 08-07398-03
Control No. 135354

Robert L. Sloan
President and Chief Executive Officer
Sibley Memorial Hospital
5255 Loughboro Road, N.W.
Washington, DC 20016-2695

SUBJECT: ISSUANCE OF LICENSE RENEWAL, CONTROL NO. 135354

Dear Mr. Sloan:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers. Please note the following:

1) Palladium-103 and Germanium-68 are accelerator produced and regulated by the state. You should contact your state agency for licensing these radionuclides.
2) Your Americium-241 and Barium-133 sources have activities less than 30 millicuries and are licensed under 10 CFR 35.65 “Calibration, reference, and transmission sources.” Therefore, they are no longer specifically listed on your license.
3) As required by 10 CFR 35.615(i), an authorized medical physicist and an authorized user must be physically present during the initiation of all patient treatments involving the high dose rate remote afterloader unit (HDR).
4) You did not provide a description of shielded facilities used for radiopharmaceutical therapy and manual brachytherapy when the patient cannot be release pursuant to 10 CFR 35.75. If a patient cannot meet the criteria to be released in accordance with 10 CFR 35.75, then contrary to statements made in your letter dated January 13, 2005, they must be housed in a patient room that has been specifically described in your license. Since facilities used to house therapy patients were not described, your license currently prohibits your use of therapeutic radiopharmaceuticals and manual brachytherapy to outpatients only. You must amend your license and describe your facilities if inpatient care is necessary.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, “Request for Taxpayer Identification Number,” is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the

representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., personnel training program, HDR full calibration, inventory, package opening, and source calibration procedures will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify the NRC in writing when:

   a) an authorized user, authorized nuclear pharmacist, authorized medical physicist or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;

   b) the mailing address changes;

   c) the name on the license changes; or

   d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).

3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license

   a) when you decide to terminate all activities involving materials authorized under the license; or

   b) if you decide not to acquire or possess and use authorized material.

4. Request and obtain a license Amendment before you:

   a) permanently change Radiation Safety Officers;

   b) receive byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c) add or change the areas of use, except as allowed by 10 CFR 35.13(e) and with the appropriate notification described in 10 CFR 35.14(b)(4);

d) change the name or ownership of your organization;

e) change the address(es) of use identified on the license;

f) receive, prepare, or use byproduct material for a type of use that is not authorized on the license;

g) permit anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist, except as allowed by 10 CFR 35.13(b) and with the appropriate notification described in 10 CFR 35.14(a); or

h) revise procedures required by 10 CFR 35.610, 35.642, 35.643, or 35.645, as applicable, where such revision reduces radiation safety.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Amendment No. 24
2. 10 CFR Parts 19, 20, 21, 30, 33, 35, 71, 170, and 171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974
5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)

cc:
Dean Rodman, M.D., Radiation Safety Officer

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OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	RRagland/RCR1		PLanzisera/PAN					
DATE	1/14/05		1/14/05					

OFFICIAL RECORD COPY

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the application dated July 19, 2004,
1. Sibley Memorial Hospital	3. License number 08-07398-03 is amended in its entirety to read as follows:
2. 5255 Loughboro Road, N.W. Washington, D.C. 20016-2695	4. Expiration date January 31, 2015
	5. Docket No. 030-14754 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 500 millicuries
D. Iodine 125 permitted by 10 CFR 35.400	D. Sealed Sources (Amersham Health Model 6711)	D. 500 millicuries
E. Iridium 192 permitted by 10 CFR 35.600	E. Sealed Sources [Nucletron Model 105.002 (manufactured by Mallinckrodt Medical B.V. or AEA Technology, Inc.)]	E. 12 curies per source and 22 curies total

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

C. Any iodine-131 study or procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75.

D. Any manual brachytherapy procedure permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75.

E. One source for medical use permitted by 10 CFR 35.600, in a Nucletron Corporation Model 105.999 remote afterloader unit. The source activity may not exceed 10 curies at the time of installation. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

CONDITIONS

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
08-07398-03

Docket or Reference Number
030-14754

Amendment No. 24

10. Licensed material may be used or stored only at the licensee's facilities located at 5255 Loughboro Road, N.W., Washington, D.C.

11. The Radiation Safety Officer for this license is Dean Rodman, M.D.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

    B. The following individuals are authorized users for medical use as indicated:

Authorized Users	Material and Use
Dean Rodman, M.D.	35.100; 35.200; 35.300
Steven Brick, M.D.	35.100; 35.200; 35.300
Irene Gage, M.D.	Iodine 125 for manual brachytherapy procedures permitted by 35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit
Angela Katz, M.D.	Iodine 125 for manual brachytherapy procedures permitted by 35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit
Gregory Sibley, M.D.	Iodine 125 for manual brachytherapy procedures permitted by 35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit
Robert H. Paley, M.D.	35.100; 35.200
Richard D. Newman, M.D.	35.100; 35.200
Richard R. Drummond, M.D.	35.100; 35.200
Christopher P. Rothstein, M.D.	35.100; 35.200
Julia J. Muskie, M.D.	35.100; 35.200
Brian G. Johnson, M.D.	35.100; 35.200
Janice J. Hwang, M.D.	35.100; 35.200

MATERIALS LICENSE
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C. The following individuals are authorized medical physicists as indicated:

Authorized Medical Physicists	Material and Use
Yue Sonya Cong, Ph.D.	Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training
Jordie Keck, M.S.	Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated July 19, 2004 (renewal - ML042150108)
B. Letter dated January 4, 2005 (renewal)
C. Letter dated January 13, 2005 (renewal)

For the U.S. Nuclear Regulatory Commission

Date January 14, 2005

By ***Original signed by Penny Lanzisera***

Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406