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

January 15, 2004

Docket No. 03003045 License No. 37-05125-01
Control No. 134137

Angela Bontempo
President and Chief Executive Officer
Saint Vincent Health Center
232 West 25th Street
Erie, PA 16544

SUBJECT: SAINT VINCENT HEALTH CENTER, ISSUANCE OF LICENSE AMENDMENT, CONTROL NO. 134137

Dear Ms. Bontempo:

This refers to your license amendment request. Enclosed with this letter is the amended license. It is our understanding that Nucletron Corporation has revised their sealed source and device registry and changed the source identifier for your remote afterloader unit. In addition, an additional source manufacturer has been added on the registry. If you require this new source, please amend your license to list the new sources.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. 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.

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

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html.

Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Enclosure: Amendment No. 70

cc:
Raymond A. Halt, M.D., Radiation Safety Officer

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DATE	01/15/2004		01/15/2004					

OFFICIAL RECORD COPY

Amendment No. 70

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 letter dated December 1, 2003,
1. Saint Vincent Health Center	3. License number 37-05125-01 is amended in its entirety to read as follows:
2. 232 West 25th Street Erie, Pennsylvania 16544	4. Expiration date October 31, 2013
	5. Docket No. 030-03045 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. 1,000 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (Prostaseed Model I125-SL/ Imagyn Model ISS 12501 and IS 12501)	D. 2,000 millicuries
E. Any byproduct material permitted by 10 CFR 35.500	E. Sealed sources (Norland Corp. Model N1077; DuPont Pharma Model NES 8412 or North American Scientific Model MED 3601)	E. 1.8 curies per source and 4 curies total
F. Iridium 192 permitted by 10 CFR 35.600	F. Sealed source (Byk Mallinckrodt Model CIL BV)	F. 12 curies per source and 24 curies total
G. Any byproduct material permitted by 10 CFR 31.11	G. Prepackaged Kits	G. 3 millicuries

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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
H. Strontium 90/Yttrium 90	H. Sealed sources (BEBIG Model Sr0.S03 or AEAT SICW.2)	H. 5 millicuries per source and 800 millicuries total
I. Cobalt-60 permitted by 10 CFR 35.600	I. Sealed Sources (General Electric AB Elekta Model 43047 or Elekta Models 43047 and 43685)	I. 36 curies per source and 9900 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 diagnostic study or therapy procedure permitted by 10 CFR 35.300.
D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
F. One source for medical use permitted by 10 CFR 35.600, in a Nucletron MicroSelectron remote afterloader unit. The source activity may not exceed 10 Ci curies at the time of installation. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
G. In vitro studies.
H. For medical use in a Novoste A1000 series device for intravascular brachytherapy.
I. For medical use permitted by 10 CFR 35.600, in a Leksell Gamma System Model 24001 Type C gamma stereotactic radiosurgery unit. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery unit.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 232 West 25th Street, Erie, Pennsylvania.

11. The Radiation Safety Officer for this license is Raymond A. Halt, M.D.

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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
Floyd Hyatt, M.D.	35.100; 35.200; 35.300; 35.500 In vitro studies
Raymond A. Halt, M.D.	35.100; 35.200; 35.300; 35.500 In vitro studies
John L. Hill, M.D.	35.100; 35.200 In vitro studies
Barry Parks, M.D.	35.100; 35.200 In vitro studies
Jeffery I. Blake, M.D.	35.200; 35.500
James P. Mackrell, M.D.	35.200; 35.500
Richard S. Kocan, M.D.	35.100; 35.200 In vitro studies
David E. Oppenheim, M.D.	35.100; 35.200; 35.500 In vitro studies
Ranjit S. Dhaliwal, M.D.	35.400 Iridium 192 for uses in a high dose rate remote afterloader unit; Strontium 90/ Yttrium 90 for intravascular brachytherapy procedures
Conrad James Stachelek, Ph.D., M.D.	35.400 Iridium 192 for uses in a high dose rate remote afterloader unit; Strontium 90/ Yttrium 90 for intravascular brachytherapy procedures
Matthew Thomas, M.D.	35.100; 35.200 In vitro studies

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Authorized Users	Material and Use
Robert M. Fine, M.D.	35.400 Iridium 192 for uses in a high dose rate remote afterloader unit; Strontium 90/ Yttrium 90 for intravascular brachytherapy procedures; Cobalt 60 for medical uses in a gamma stereotactic radiosurgery unit
Peter M. Laye, M.D.	35.400 Iridium 192 for uses in a high dose rate remote afterloader unit; Strontium 90/ Yttrium 90 for intravascular brachytherapy procedures

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

Authorized Medical Physicists	Material and Use
Ronald Scala, M.S.	Iridium 192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an intravascular brachytherapy afterloader device for calibrations, spot-checks, and training
David Hinckley, M.S.	Iridium 192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an intravascular brachytherapy afterloader device for calibrations, spot-checks, and training; Cobalt 60 in a gamma stereotactic radiosurgery unit for calibrations, spot-checks, and training
Stephen H. Mahood, M.S.	Iridium 192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an intravascular brachytherapy afterloader device for calibrations, spot-checks, and training
Neal Smarra, M.S.	Iridium 192 in a high dose rate remote afterloader unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an intravascular brachytherapy afterloader device for calibrations, spot-checks, and training

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D. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

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 financial assurance for decommissioning.

14. In lieu of 10 CFR 35.404(b), immediately after retracting the source from the patient into its shielded position in the remote afterloading device or Beta-Cath System intravascular brachytherapy device, a radiation survey shall be made of the patient and the remote afterloading device or Beta-Cath System intravascular brachytherapy device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.2404.

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

16. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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17. 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 June 20, 2003
    B. Letter dated August 7, 2003
    C. Letter dated August 22, 2003
    D. Application dated August 22, 2003
    E. Letter dated October 3, 2003
    F. Letter dated October 10, 2003

For the U.S. Nuclear Regulatory Commission

Original signed by Penny Lanzisera

Date January 15, 2004 By _____

Penny Lanzisera
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406