

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 2, 2006

Docket No. 03003142 License No. 37-11507-01

Control No. 138980

C. Richard Hartman, M.D. Chief Executive Officer Community Medical Center 1800 Mulberry Street Scranton, PA 18510

SUBJECT: COMMUNITY MEDICAL CENTER, LICENSE AMENDMENT, CONTROL NO.

138980

Dear Dr. Hartman:

This refers to your license amendment request. Enclosed with this letter is the amended license.

In your letter dated June 12, 2006, you requested authorization for IsoAid Advantage I125 and Best Industry Model 2301 iodine-125 manual brachytherapy sources. Please note that the Sealed Source Device Registry lists the current manufacturers and model numbers for these sealed sources as IsoAid, L.L.C. Model IAI-125A and Best Medical International, Inc. Model 2301, respectively, and the sources will be listed as such on your license.

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).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select Nuclear Materials; Medical, Academic, and Industrial 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 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

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Original signed by Donna M. Janda

Donna M. Janda Health Physicist Medical Branch

Division of Nuclear Materials Safety

Enclosure:

Amendment No. 53

CC:

David Sabbar, M.D., Radiation Safety Officer

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DOCUMENT NAME: E:\Filenet\ML062150169.wpd

SUNSI Review Complete: <u>DJanda</u>
After declaring this document "An Official Agency Record" it <u>will</u> be released to the Public.

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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 v	vith t	the letters dated			
				June 5, 2006, and June 12, 2006,					
. (Community Medical Center			3. License number 37-11507-01 is amended in					
			ARR	its entirety to read as follows:					
		-1	EAR R	-901					
		10,		4. Expiration date A	A -				
,	Scranton, Pennsylvania 18510			5. Docket No. 030	-031	142			
	9			Reference No.	1	٥			
	Li s			100		<u></u>			
6.	Byproduct, source, and/or special nuclear material	7.	Chemical and/or pl	nysical form	8.	Maximum amount that licensee may possess at any one time under this license			
Α.	Any byproduct material permitted by 10 CFR 35.100	A.	Any	3 16/1/2	A.	As needed			
Β.	Any byproduct material permitted by 10 CFR 35.200	В.	Any	5	B.	As needed			
C.	lodine 131 permitted by 10 CFR 35.300	C.	Any	AR S	C.	100 millicuries			
D.	Any byproduct material permitted by 10 CFR 35.400	D.	Sealed Source Brachytherapy 1251; Best Med International, Ir Implant Scienc Model 3500; or Model IAI-125A	Model STM dical nc. Model 2301; es Corporation IsoAid, L.L.C.	D.	5 curies			
Ε.	Any byproduct material permitted by 10 CFR 35.500	E.	Sealed Source Meyers Squibb Imaging Model	Medical	E.	1 curie per source and 2 curies total			
F.	Strontium 90/Yttrium 90	F.	Sealed Source Model Sr0.S03 Series (SICW.	or AEAT SICW	F.	5 millicuries per source and 800 millicuries total			

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- 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 in quantities less than or equal to 33 millicuries 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. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. For medical use in Novoste A1000 Series models for intravascular brachytherapy.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 1800 Mulberry Street, Scranton, Pennsylvania.
- 11. Licensed material is only authorized for use by, or under the supervision of:

Authorized Users

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.

Material and Use

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

Olindo J. Preli, M.D.	35.200
Charles N. Barax, M.D.	35.100; 35.200
Jose L. Gonzalez, M.D.	35.100; 35.200
Javed Iqbal Malik, MB,BS	35.100; 35.200
Frank Piro, M.D.	35.100; 35.200
Burton U. Marks, D.O.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies and treatment of hyperthyroidism and cardiac dysfunction; 35.500
David Sabbar, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies and treatment of hyperthyroidism and cardiac dysfunction

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Authorized Users Material and Use

Harmar D. Brereton, M.D. 35.400

Madhava Baikadi, M.D. 35.400; Strontium 90/Yttrium 90 for intravascular

brachytherapy procedures

Chi Keung Tsang, M.D. 35.400; Strontium 90/Yttrium 90 for intravascular

brachytherapy procedures

Michael A. Burke, M.D. 35.400

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

Authorized Medical Physicists

Carla Setto-Scofield, M.S.

Weimin Chen, Ph.D.

Material and Use

Strontium-90/Yttrium-90 in an intravascular brachytherapy device for calibrations and training

Strontium-90/Yttrium-90 in an intravascular brachytherapy device for calibrations and training

- 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.
- 12. The Radiation Safety Officer for this license is David Sabbar, M.D.
- 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."

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- 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 February 23, 2005 (ML051150187)
 - B. Facsimile dated July 18, 2005 (ML052000497)
 - C. Facsimile dated August 15, 2005 (ML0522800990)
 - D. Facsimile dated August 22, 2005 (ML052350931)



For the U.S. Nuclear Regulatory Commission

Date	August 2, 2006	Ву	Original signed by Dolina III. Garida	
			D 14 1 1	Τ

Donna M. Janda Medical Branch Division of Nuclear Materials Safety Region I King of Prussia, Pennsylvania 19406

Original signed by Donna M. Janda