



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

May 24, 2007

Docket No. 03013060
Control No. 140161

License No. 07-17618-01

Doug Connell
Interim Chief Executive Officer
Nanticoke Memorial Hospital
801 Middleford Road
Seaford, DE 19973

SUBJECT: NANTICOKE MEMORIAL HOSPITAL, LICENSE AMENDMENT, CONTROL NO.
140161

Dear Mr. Connell:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please assure that Louis F. Owens, M.D., your Radiation Safety Officer, receives training in radiation safety, regulatory issues, and emergency procedures pertaining to Iodine 125 brachytherapy.

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 **Regulations, Guidance, and Communications**. You may also 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,

Original signed by Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 15

D. Connell
Nanticoke Memorial Hospital

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cc:
Louis F. Owens, Jr., M.D., Radiation Safety Officer

D. Connell
Nanticoke Memorial Hospital

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DATE	5/24/07		5/24/07					

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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 1. Nanticoke Memorial Hospital 2. 801 Middleford Road Seaford, Delaware 19973	In accordance with the letter dated February 5, 2007, 3. License number 07-17618-01 is amended in its entirety to read as follows: 4. Expiration date June 30, 2013 5. Docket No. 030-13060 Reference No.
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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 |
| 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. Iodine 125 permitted by 10 CFR 35.400 | C. Sealed Sources (See Condition 12) | C. 1000 millicuries |
| D. Any byproduct material permitted by 10 CFR 35.500 | D. Sealed Sources (DuPont Merck Model NES 8426) | D. 36 millicuries per source, 500 millicuries total |
| E. Any byproduct material permitted by 10 CFR 31.11 | E. Prepackaged Kits | E. 5 millicuries |

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 manual brachytherapy procedure permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75.
- D. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- E. In vitro studies.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
07-17618-01Docket or Reference Number
030-13060

Amendment No. 15

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 801 Middleford Road, Seaford, Delaware.
11. The Radiation Safety Officer for this license is Louis F. Owens, Jr., M.D.
12. Sealed sources authorized pursuant to the condition of the license shall be in accordance with the following table:

<u>Radionuclide</u>	<u>Source Model Number</u>	<u>Maximum Activity Per Source</u>
Iodine 125	Amersham Health/Medi-Physics, Inc. Model 6711 (OncoSeed)	270 millicuries
	Amersham Health/Medi-Physics, Inc. Model 6733 (EchoSeed)	71.2 millicuries
	North American Scientific, Inc. Model MED3631	25 millicuries
	Best Medical International, Inc. Model 2300 Series	110 millicuries
	BEBIG Model 125.S06	100 millicuries
	Mills Biopharmaceuticals, LLC Model I-125 SL and I-125 SH	150 millicuries
	IsoAid, LLC Model IAI-125A	10 millicuries
	Bard Brachytherapy, Inc. Model STM 1251	15 millicuries
	DRAXIMAGE, LLC Model LS-1 (manufactured by Draxis Specialty Pharmaceuticals, Inc.)	75 millicuries
	Implant Sciences Corporation Model 3500	7.5 millicuries
	IsoStar Texas, Inc. Model IS-125 Series	10 millicuries
	International Brachytherapy SA Model 1251L	6.5 millicuries

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<u>Radionuclide</u>	<u>Source Model Number</u>	<u>Maximum Activity Per Source</u>
Iodine 125	Syncor Pharmaceuticals, Inc. Model BT-125-1	6 millicuries
	Amersham/Medi-Physics, Inc. Model 6702	195 millicuries

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

- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Louis F. Owens, Jr., M.D.	35.100; 35.200; 35.500; <u>In vitro</u> studies
Mark L. Sobczak, M.D.	35.400
Manoj Jain, M.D.	35.400

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. 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.

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16. 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 March 27, 2003 (ML030970692)
- B. Letter dated June 4, 2003 (ML031671344)
- C. Letter dated February 5, 2007 (ML070650669)



For the U.S. Nuclear Regulatory Commission

Date May 24, 2007By ***Original signed by Sandra Gabriel***

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406