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

August 9, 2006

Docket No. 03002431 License No. 29-01101-03
Control No. 138938

Jeffrey Goodwin
Chief Executive Officer
Warren Hospital
185 Roseberry Street
Phillipsburg, NJ 08865

SUBJECT: WARREN HOSPITAL, LICENSE AMENDMENT, CONTROL NO. 138938

Dear Mr. Goodwin:

This refers to your license amendment request dated May 25, 2006. Enclosed with this letter is the amended license. We have approved Drs. Little, Mascarenhas, Singh, Elmi, C. Patel, Rohatgi, and Khalighi as authorized user under 35.100 and 35.200.

Please note that Dr. Arthur Popkave is not an Authorized User on the license # 29-30622-01 and Dr. Pradeep S. Ghia is not an Authorized User on the license # 37-30276-01 as stated in your letter dated May 25, 2006.

Please note that in support of your request to authorize Drs. Arthur Popkave, Nainesh Patel, Devendra K. Amin and Pradeep S. Ghia for materials permitted under 10 CFR 35.100 and 35.200, please provide one of the following, as applicable:

10 CFR 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements, involving--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

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,

Original signed by Shirley Xu

Shirley Xu
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 28

cc:
Mitchell Rabinowitz, M.D., Radiation Safety Officer

DOCUMENT NAME: G:\Docs\Mailed\Lic Cvr Letter\l29-01101-03.138938.08112006.wpd

SUNSI Review Complete: SXu
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Amendment No. 28

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 May 25, 2006,
1. Warren Hospital	3. License number 29-01101-03 is amended in its entirety to read as follows:
2. 185 Roseberry Street Phillipsburg, New Jersey 08865	4. Expiration date August 31, 2012
	5. Docket No. 030-02431 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 included in 10 CFR 35.100	A. Any radiopharmaceutical included in 10 CFR 35.100	A. As needed
B. Any byproduct material included in 10 CFR 35.200	B. Any radiopharmaceutical included in 10 CFR 35.200	B. As needed
C. Iodine 125	C. Any brachytherapy source identified in 10 CFR 35.400	C. 1000 millicuries

9. Authorized use:

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
B. Any imaging and localization procedure approved in 10 CFR 35.200.
C. Any brachytherapy procedure approved in 10 CFR 35.400.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 185 Roseberry Street, Phillipsburg, New Jersey.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-01101-03

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030-02431

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11. 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 the materials and uses indicated:

Authorized Users	Material and Use
Mitchell Rabinowitz, M.D.	35.100; 35.200
Joseph M. Bucich, M.D.	35.100; 35.200
Patrick M. Inverso, M.D.	35.100; 35.200
Kenneth A. Cohen, M.D.	35.100; 35.200
Stuart Miller, M.D.	35.100; 35.200
Matthew S. Pollack, M.D.	35.100; 35.200
Thomas Little, M.D.	35.100; 35.200
Daniel Mascarenhas, M.D.	35.100; 35.200
Narpinder Singh, M.D.	35.100; 35.200
Farhad Elmi, M.D.	35.100; 35.200
Chandulal Patel, M.D.	35.100; 35.200
Rajeev Rohatgi, M.D.	35.100; 35.200
Koroush Khalighi, M.D.	35.100; 35.200
Aruna Patel, M.D.	35.400
Stewart Berkowitz, M.D.	35.400

12. The Radiation Safety Officer for this license is Mitchell Rabinowitz, 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), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

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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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 29, 1991
    B. Letter dated June 17, 1992
    C. Letter dated July 15, 1996
    D. Letter dated November 11, 1996
    E. Letter dated April 28, 1997
    F. Letter dated November 28, 2000 except Quality Management Program
    G. Letter dated January 8, 2001

For the U.S. Nuclear Regulatory Commission

Date August 9, 2006

By ***Original signed by Shirley Xu***

Shirley Xu
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406