



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

June 24, 2005

Docket No. 03033000
Control No. 137106

License No. 29-30003-01

Kock-Yen Tsang, M.D.
Medical Director
Ocean Heart Imaging
9 Hospital Drive
Toms River, NJ 08755

SUBJECT: OCEAN HEART IMAGING, LICENSE AMENDMENT, CONTROL NO. 137106

Dear Dr. Tsang:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that your license was written in a format compatible with the revised 10 CFR Part 35, effective October 24, 2002.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. Please note 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., calibration of dose calibrators, 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. 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 available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/who-we-are/governing-laws.html> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

K. Tsang
Ocean Heart Imaging

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Thank you for your cooperation.

Sincerely,

Original signed by Steven Courtemanche

Steven Courtemanche
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 7

cc:
John P. West, Radiation Safety Officer

DOCUMENT NAME: G:\Docs\Mailed\Lic Cvr Letter\29-30003-01.137106.06262005.wpd

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NAME	SCourtemanche/src						
DATE	6/24/2005						

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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.

<p style="text-align: center;">Licensee</p> <p>1. Ocean Heart Imaging</p> <p>2. 9 Hospital Drive Toms River, New Jersey 08755</p>	<p>In accordance with the letters dated May 19, 2005 and June 20, 2005,</p> <p>3. License number 29-30003-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2013</p> <hr/> <p>5. Docket No. 030-33000 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct Material permitted by 10 CFR 35.200</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p>
<p>9. Authorized use:</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p>		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 9 Hospital Drive, Toms River, New Jersey.
- 11. The Radiation Safety Officer for this license is John P. West, CNMT.
- 12. 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:

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-30003-01

Docket or Reference Number
030-33000

Amendment No. 7

Users

Kock-Yen Tsang, M.D.

Najib Alturk, M.D.

Murat Karatepe, M.D.

Material and Use

35.100; 35.200

35.200

35.100; 35.200

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 January 20, 2003 (ML030270305)
 B. Letter dated March 27, 2003 (ML030910095)
 C. Letter dated April 1, 2003 (ML030980401)
 D. Letter dated June 20, 2005

For the U.S. Nuclear Regulatory Commission

Date June 24, 2005

By Original signed by Steven Courtemanche
 Steven Courtemanche
 Commercial and R&D Branch
 Division of Nuclear Materials Safety
 Region I
 King of Prussia, Pennsylvania 19406