



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
612 EAST LAMAR BLVD, SUITE 400  
ARLINGTON, TEXAS 76011-4125

February 17, 2009

Hiro Makino, M.D., Inc.  
ATTN: Ronald Frick  
Radiation Safety Officer  
98-1079 Moanalua Road, Suite 655  
Aiea, Hawaii 96701

SUBJECT: LICENSE AMENDMENT AND NOTIFICATION PER 10 CFR 35.14(b)(5)

Please find enclosed Amendment No. 02 to NRC License No. 53-29263-01, **acknowledging your notification for changing to, and adding areas of use in Suite 655, and authorizing the floor plans under License Condition 15.C. of your license.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review the enclosed document carefully and be sure that you understand all conditions. If there are any questions, please contact me at 817-276-6552.

**The NRC medical list server has been set up. The list server will send automatic e-mail notifications of medical-related generic communications, Federal Register Notices, and NMSS/FSME newsletters as they are published. Anyone may subscribe/unsubscribe to the new medical list server by sending an e-mail to [medical-gc@nrc.gov](mailto:medical-gc@nrc.gov) with "Subscribe" or "Unsubscribe" in the subject line.**

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:
  - a. The date that the licensee permits an individual to work as an authorized user under 10 CFR 35.13(b)(1) through (b)(4);
  - b. An authorized user or a Radiation Safety Officer permanently discontinues duties under the license or has a name change;
  - c. The licensee's mailing address changes;
  - d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or
  - e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

NRC no longer publishes the NRC Rules and Regulations loose leaf supplements. However, an electronic version of the NRC's regulations is available on the NRC Web site at [www.nrc.gov](http://www.nrc.gov). Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,



Rachel S. Browder, Health Physicist  
Nuclear Materials Safety Branch B

Docket: 030-37462  
License: 53-29263-01  
Control: 472030

Enclosure: As stated

**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. Hiro Makino, M.D., Inc.</p> <p>2. 98-1079 Moanalua Road, Suite 655 Aiea, Hawaii 96701</p>	<p>In accordance with letter dated October 23, 2008</p> <p>3. License number 53-29263-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2017</p> <p>5. Docket No. 030-37462 Reference No.</p>
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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 35.200  | A. Any                           | A. As needed   |

9. Authorized use:
- A. Any imaging and localization study permitted by 10 CFR 35.200

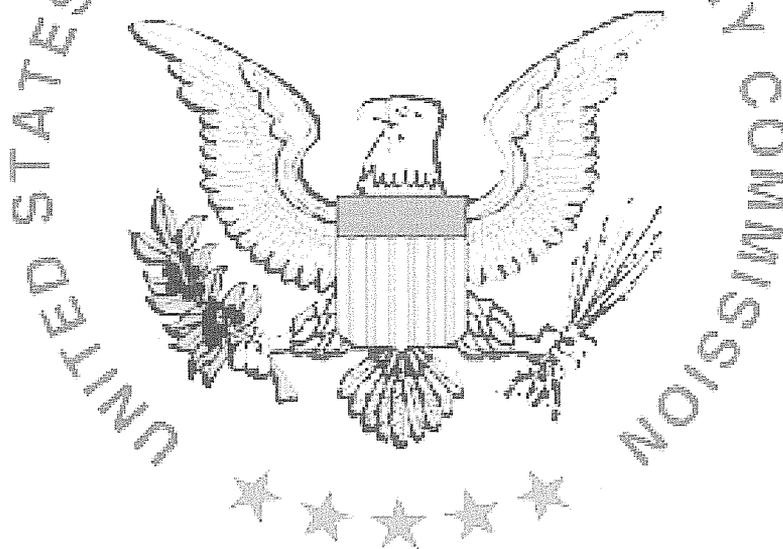
**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 98-1079 Moanalua Road, Suite 350 and Suite 655, Aiea, Hawaii. (Oahu Island)
11. The Radiation Safety Officer for this license is Ronald Frick.
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 the material and medical uses indicated: |                         |                          |        |  |
| <table border="0" style="width: 100%;"> <tr> <td style="text-align: center;"><u>Authorized Users</u></td> <td style="text-align: center;"><u>Material and Use</u></td> </tr> <tr> <td style="text-align: center;">Eugene J. Ichinose, M.D.</td> <td style="text-align: center;">35.200</td> </tr> </table> | <u>Authorized Users</u>  | <u>Material and Use</u> | Eugene J. Ichinose, M.D. | 35.200 |  |
| <u>Authorized Users</u>  | <u>Material and Use</u>  |                         |                          |        |  |
| Eugene J. Ichinose, M.D.   | 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 financial assurance for decommissioning.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
53-29263-01Docket or Reference Number  
030-37462

Amendment No. 02

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 April 24, 2007 (ML071270129)  
B. Letter dated December 13, 2007 (ML0800802030)  
C. Letter dated October 23, 2008 (ML090300149)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: February 17, 2009By: *Rachel S. Browder*Rachel S. Browder, Health Physicist  
Nuclear Materials Safety Branch B  
Region IV  
Arlington, Texas 76011-4125