



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION IV
1600 E. LAMAR BLVD
ARLINGTON, TX 76011-4511

April 6, 2018

Mr. Dale J. Schippers, M.S.
Radiation Safety Officer
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, HI 96813

SUBJECT: LICENSE AMENDMENT

Dear Mr. Schippers:

Please find enclosed Amendment Number 76 to NRC License Number 53-16533-02 deleting previous Items 6.F., 7.F., 8.F., and 9.F.; adding a location of use; adding authorized users; and adding an authorization of use for Condition 10.C., as requested. An environmental assessment for this licensing action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-200-1132 if you have any questions about this license.

Please note that the isotope, manufacturer and model of sealed sources permitted by 10 CFR 35.400 for manual brachytherapy are now line listed separately; therefore, Items 6.E., 7.E., 8.E., and 9.E. through 6.L., 7.L., 8.L., and 9.L. are re-alphabetized.

In addition, please note that Item 7.J. is updated with the correct manufacturer as specified in the Sealed Source and Device Registry Sheet. The registry sheet under "limitations and other considerations of use" state that this source was previously distributed by Amersham Corporation.

Also, please note that the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance dated February 12, 2016, Revision 9 is the most current licensing guidance. Please note that if you are currently authorized to use these products that is committed by license condition to following provisions in a previous revision of this guidance, you may request a license amendment to commit to following this revision of the guidance instead. The licensee must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

**The enclosure transmitted
herewith contains Official Use
Only – Security-Related
Information. When separated
from this enclosure, this
document is decontrolled.**

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement is not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

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. Notify NRC in writing of any change in mailing address.
3. By 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;
 - b. If you decide not to acquire or possess and use authorized material; or
 - c. When no principal activities under the license have been conducted for a period of 24 months.
4. 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, an authorized nuclear pharmacist or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);
 - b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist 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

D. Schippers

-3-

- 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.
5. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;
 - c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or
 - d. Change the name or ownership of your organization.
 6. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

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/about-nrc/regulatory/enforcement/enforce-pol.html>.

~~OFFICIAL USE ONLY – SECURITY-RELATED INFORMATION~~

D. Schippers

-4-

An electronic version of the NRC's regulations is available on the NRC Web site at 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).

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 with "Subscribe" or "Unsubscribe" in the subject line.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through the NRC's Agencywide Documents Access and Management System (ADAMS). The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/>. Pursuant to NRC's RIS 2005-31, this letter and its enclosed materials license will not be made publicly available.

Thank you for your cooperation.

Sincerely,

/RA/

Jacqueline D. Cook, Senior Health Physicist
Materials Licensing and Inspection Branch

Docket: 030-14522/030-34081
License: 53-16533-02
Control: 602216

Enclosure: As stated

~~OFFICIAL USE ONLY – SECURITY-RELATED INFORMATION~~