



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

May 21, 2007

Rocky Mountain Oncology
ATTN: Alan G. Douglas, M.S.
Radiation Safety Officer
6501 East Second Street
Casper, WY 82609

SUBJECT: NEW LICENSE

Please find enclosed, NRC License No. 49-29254-01. This license authorizes the possession only of iridium-192 sealed source for the Varian GammaMed plus HDR afterloader device. The new license authorizes (pending completion of initial vendor training for new users) Dr. John Purviance as an authorized user for 10 CFR 35.600 (HDR only) use. The licensed material may only be stored at your facility in Casper, WY. 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 errors or if you have any questions, please contact me at 817-276-6552.

In order to authorize the use of the Varian GammaMed plus HDR afterloader device, the regulations in 10 CFR 35.615 requires that an authorized medical physicist, who has received training in the operation and emergency response for the unit, is to be physically present during the initiation of all patient treatments involving the unit and is to be immediately available in the event of an emergency involving the unit. While the documentation of training and experience submitted for Mr. Alan Douglas lists a history of involvement as a medical physicist with HDR treatment deliveries, the regulations at that time did not require the medical physicist to be specifically listed on a radioactive materials license. However, under the revised regulations in 10 CFR Part 35, the medical physicist is now required to be authorized on the radioactive material license. The NRC has issued a Regulatory Issues Summary (RIS) 2006-26, which addresses this issue. The RIS is entitled "Training and experience and grandfather provisions for authorized medical physicists under 10 CFR Part 35." This RIS may be located on the NRC website at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/>. Additionally, a copy of the RIS 2006-26 is enclosed for your review. Please refer to this RIS and submit a completed NRC Form 313A or equivalent, documenting the preceptor attestation as described in 10 CFR 35.51(b).

Additionally, please clarify your operating procedures to reflect the regulatory requirement in 10 CFR 35.615, which states in part, that a medical physicist and either an authorized user or a physician under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, is to be physically present during the initiation of all patient treatments involving the unit and immediately available in the event of an emergency. The regulations do not recognize the Radiation Safety Officer as being one of the individuals required to be present or immediately available.

The NRC can not authorize Dr. Robert L. Tobin for 10 CFR 35.600 uses at this time. The documentation of training and experience for Dr. Tobin did not indicate supervised participation with a completed preceptor attestation for HDR cases. The supervised work and clinical experience should include, but is not limited to, treatment plans, calculation of treatment doses, and administration of proper dosages. The NRC does not recognize the observation of HDR cases. Please complete the highlighted portions of the enclosed NRC Form 313A (AUS), as a separate license amendment request to add Dr. Tobin as an authorized user.

The NRC needs your Taxpayer Identification Number in order to make payments (refunds). Please complete and return NRC Form 531, "Request for Taxpayer Identification Number," which is enclosed for your convenience.

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

- 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/what-we-do/regulatory/enforcement/enforc-pol.pdf>.

The 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. 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.

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 NRC's electronic document repository (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, the enclosed materials license will not be made publicly available.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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,

/RA/

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-37415
License: 49-29254-01
Control: 471271

Enclosures: As stated