

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352



DEC 03 2013

Edward F. Downey, Jr., D.O.
Radiation Safety Officer
1000 West Tenth Street
Rolla, MO 65401

Dear Dr. Downey:

Enclosed is Amendment No. 37 to your NRC Material License No. 24-18295-01-01 in accordance with your request. Please note that the major changes made to your license are printed in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

- A. Please note that, at this time, we must make a change to your authorization in Subitem Nos. 6 through 9 C.

Please submit a written response, currently dated and signed by a senior management representative, to enable us to effect these changes within 30 days of the date of this letter (about the first week of January 2014). Please address your response to my attention as "additional information to control number 581674.)

If a different timeframe is necessary, please contact me at (630) 829-9841 to discuss alternative arrangements.

1. We must change Subitem No. 8.C. of your license so that it shows one total possession limit for all materials permitted by 10 CFR 35.300. Subitem No. 8.C. currently shows "As needed (not to exceed 1 curie of iodine-131)."

Please specify one total possession limit for all materials permitted by 10 CFR 35.300. Your possession limit should be realistic for your needs and circumstances and include activity factored into waste streams for decay-in-storage.

2. Please note that we separated out your authorizations for materials in 10 CFR 35.400, and accorded each radionuclide a line item, including manufacturer's names and model numbers and individual possession limits.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

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So your license now lists Subitem Nos. 6 through 9 D, E and F for iridium-192, iodine-125, and palladium-103, whereas in Amendment No. 36 these were combined into Subitem No. 6 through 9 D only.

Please note that the company formerly known as "Mills Biopharmaceuticals" is now known as "Core Oncology, Inc."

Please also note that we were unable to verify your previously authorized source in Subitem No. 7D on Amendment No. 36, listed as "Mills Biopharmaceuticals, Inc., Model Pd-103 SL." I attempted to reach Jason Sharp by telephone on December 3, 2013, to discuss this matter further, determine whether you had any of these sources in your possession at this time and if you wanted to continue this authorization. Unfortunately, my attempt to reach Mr. Sharp was unsuccessful.

Since we could not verify this source as licensable, we removed it from your license. If you wish to restore this source to your license, please submit full information for it, including the current manufacturer's name and model number. It would also be helpful if you can provide the Sealed Source and Device Registration (SSDR) certificate or number to assist us in verifying it. You may follow the directions in section A. above for your submittal.

B. This also refers to your letter dated September 5, 2013, which requests several changes to your license.

1. Your letter describes proposed changes to your high dose rate remote afterloading brachytherapy device(s) authorizations and operations. However, it is not entirely clear exactly what has transpired between you and the outside vendor, who your outside vendor was and their licensure, and the fate of the HDR devices you now wish to remove from your license.

In order for us to delete the authorizations for the HDR device(s) that your former outside vendor supplied, please provide specific information concerning this vendor, identify the vendor, and describe in greater detail what has transpired, including the fate of the HDR sources and devices you wish to remove. If you have further questions concerning this matter, please contact me at (630) 829-9841.

2. Your letter requests the removal of Viswanathan Subbaratnam from Condition No.12.C. However, no individual by that name is listed anywhere on your license so we cannot remove him/her.
3. Your letter requests the addition of Jeffrey S. Wyler as an Authorized Medical Physicist and states that a copy of "prior RAM License" listing him as an AMP is attached.

However, no documents were attached to your letter and no other training and experience qualifications for Mr. Wyler were included in your letter. Therefore we were unable to approve Mr. Wyler as an AMP at this time.

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If you wish to pursue this matter, please follow the instructions given in section A. above and provide sufficient training and experience documentation to support your request to add Mr. Wyler as an AMP on your license. 10 CFR 35.13, 35.14, 35.51, 35.57 and NUREG 1556, Vol. 9, Rev. 2, Appendices B and D, and section 8.14 Item 7 may assist you.

- C. Please note that we deleted Condition No. 14, as it appeared on Amendment No. 36, because it was no longer necessary for your license.
- D. Please be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information," ... "(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

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 ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions

regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

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Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with

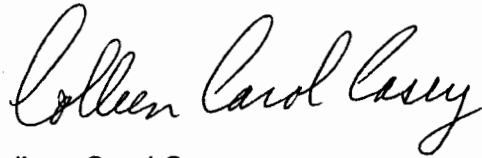
licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and 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.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 21-18295-01
Docket No. 030-14804

Enclosure:
Amendment No. 37 |