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

JAN 05 2009

Sidney D. Machefsky, M.D.
Radiation Safety Officer
St. Joseph Health Center
300 First Capitol Drive
St. Charles, MO 63301

Dear Dr. Machefsky:

Enclosed is Amendment No. 58 to your NRC Material License No. 24-15159-01 in accordance with your request. Please note that the 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.

Please note that at this time I could not approve your requests for the removal of authorization for iridium-192 in a high dose rate remote afterloading brachytherapy device at the 300 First Capitol Drive, St. Charles, Missouri location and authorization for Daniel T. Cohen, M.D. for the use of materials in 10 CFR 35.300 (limited to oral administration of iodine-131 in quantities less than or equal to 33 millicuries) because the information in your letters dated September 29, 2008 and October 27, 2008, was insufficient to complete my review.

If you wish to pursue these requests please submit the information below, addressed to my attention as "additional information to control number 317556." We will then continue our review.

I could not approve your request for the removal of authorization for iridium-192 in a high dose rate remote afterloading brachytherapy device at the 300 First Capitol Drive, St. Charles, Missouri location because, in order to do so, you will need to submit a copy of the signed and dated confirmation of receipt provided to you by the vendor or licensed party that took possession of your final HDR source for disposal. This receipt was not included in your correspondence to us dated September 29, 2008. Please submit this information in accordance with the instructions above.

Regarding Dr. Cohen's request for expanded authorization, please submit appropriate documentation demonstrating that Dr. Cohen meets the training and experience requirements in 10 CFR 35.392, 35.13, 35.14, 35.57 and/or 35.59, as appropriate.

Please refer to the regulatory requirements in 10 CFR 35.392, 35.57, 35.13 and 35.59, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your written response to demonstrate that Dr. Cohen's training and experience meet the appropriate regulatory requirements for the use of materials in 10 CFR 35.392.

If Forms 313a will be used in support of your response, please use the newly revised Forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aut\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aut).pdf)

Dr. Cohen was not approved as an AU for the use of materials in 10 CFR 35.39 (limited to oral administration of iodine-131 in quantities less than or equal to 33

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

S. Machefsky

millicuries) because we were unable to verify the preceptor's qualifications. The preceptor references Massachusetts General Hospital's license, which is an Agreement State license, that we do not have access to and it may very well be a broad scope license, i.e., it does not name AU's on its license document directly; rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.

Please submit a letter currently signed and dated by the Chair of the RSC for Massachusetts General Hospital stating which modalities Dr. Edwin L. Palmer was authorized for under the license and specifying which timeframes he held said authorization.

Please do NOT submit copies of minutes from the licensee's RSC meetings or other documents from the licensee, esp. patient records, or extraneous documentation that we must protect, per 10 CFR 2.390.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

Please also 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 or the information above please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078.

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>.

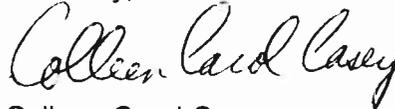
S. Machefsky

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. 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.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 24-15159-01
Docket No. 030-08664

Enclosure:

Amendment No. 58