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

APR 1 1 2017

Wallace O. Fuhrman, CNMT Radiation Safety Officer SSM Health St. Joseph Hospital – St. Charles 300 First Capitol Drive St. Charles, MO 63301

Dear Mr. Fuhrman:

Enclosed is Amendment No. 75 to your NRC Material License No. 24-15159-01 in accordance with your request.

Please 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.

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.

This also refers to your letter dated March 3, 2017, which requests authorization for Amanda Chu, M.D. as an authorized user for materials in 10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131).

We were unable to approve Dr. Chu at this time because the information provided in your letter dated March 3, 2017, was insufficient to complete our review.

If you wish to pursue this matter, please provide a complete, written response that is currently dated and signed by a senior management official for this license, pursuant to 10 CFR 35.12(a).

It should be addressed to my attention at the above address, as "additional information to control number 592811." We will then continue our review.

Dr. Chu's request to become an authorized user for materials in 10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131) must be fully supported by the description of her education, training and experience on the documents you submitted.

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

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Her supporting documents must include Forms NRC 313a (AUD, AUT), as attested to by a qualified authorized user/preceptor for the same modalities. A key part of this supporting documentation consists of verification of her preceptor, Dana Mathews, M.D., Ph.D.

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Her Forms NRC 313a (AUD and AUT) were signed by her "Supervising individual," Dana Mathews, M.D., Ph.D. on February 14, 2017, representing the University of Texas Southwestern Medical Center, license number TXL 00384, which is an Agreement State licensee.

NRC does not have direct jurisdiction over this licensee; the State of Texas does and it administers this license. NRC does not have access to this license, which is needed to assist in the verification of the preceptor, Dr. Mathews.

If this license is a broad scope medical license, then Dr. Mathew's name will not appear on the license itself. The Radiation Safety Committee for broad scope medical licenses evaluates and approves/disapproves of authorized users internally.

Please submit a complete, current, signed and un-redacted copy of the University of Texas Southwestern's license that shows it is authorized for materials in 10 CFR 35.100, 35.200 and 35.300 and either Dr. Mathew's name on this license as an authorized user for these materials or a signed, dated letter from the Chairperson of the licensee's Radiation Safety Committee attesting that Dr. Mathews was an authorized user from July 1, 2010 to June 30, 2015, when s/he supervised and preceptored Dr. Chu.

In addition, please submit another copy of Dr. Chu's specialty board certification because the copy that accompanied your letter dated March 3, 2017, appeared to have part of the "Effective Date" year cut off in the lower right hand corner.

<u>Please refer</u> to the regulatory requirements in 10 CFR 35.190, 35.290, 35.392, 35.394 and section 8.12, 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. Mathews is qualified to serve as Dr. Chu's preceptor. Part II on page D-6, paragraph one and Section V. on page D-3, second paragraph in Appendix D reference the information we are requesting and describe preceptor statements and supporting licenses for preceptors.

http://www.nrc.gov/materials/miau/med-use-toolkit.html

http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/

<u>Please do not submit</u> 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.

You will be periodically inspected by NRC. Failure to conduct your program in

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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.

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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.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify securityrelated 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/doccollections/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).

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 <u>http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</u>.

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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,

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Colleen Carol Casey Materials Licensing Branch

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

Enclosure: Amendment No. 75

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