

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532-4352

APR 1 8 2008

Tiffany A. Door, CNMT Radiation Safety Officer Metro Heart Group of St. Louis, Inc. 12855 N. Forty Road Suite 300 St. Louis, MO 63141

Dear Ms. Door:

Enclosed is Amendment No. 21 to your NRC Material License No. 24-32184-01 in accordance with your request. Please note that some of the changes made to your license are printed in **bold** font.

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.

Please note that we were unable to approve Manoj K. Eapen, M.D., and Bassam A. Roukoz, M.D. as Authorized Users for the use of materials in 10 CFR 35.200, at this time because the information in your letter dated January 10, 2008, was insufficient to complete our review.

If you wish to pursue this matter, please submit the following information, addressed to my attention and referenced as "additional information to control number 316631."

Drs. Eapen and Roukoz were not approved as Authorized Users for the use of materials in 10 CFR 35.200 because neither physician met the requirement in 10 CFR 35.290(c)(1)(ii)(G) concerning training and experience eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

<u>Please refer</u> to the regulatory requirements in 10 CFR 35. 35.290(c)(1)(ii)(G) 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 Drs. Eapen and Roukoz' training and experience meet the appropriate regulatory requirements for the modality they seek authorization for.

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(aud).pdf

<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.

T. Door

If you have any questions concerning this amendment please contact me at (630) 829-9841.

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/fag.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. 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. 24-32184-01

Docket No. 030-35037

Enclosure:

Amendment No. 21