UNITED STATES NUCLEAR REGULATORY COMMISSION

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

NOV 2 9 2012



Daniel Hoffman
Radiation Safety Officer
Mallinckrodt LLC
2703 Wagner Place
Maryland Heights, MO 63043

Dear Mr. Hoffman:

Enclosed is Amendment No. 41 to your NRC Material License No. 24-04206-05MD 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 <u>very carefully</u> and be sure that you understand all conditions. Note that there have been several changes made to your license, including requested deletions and subsequent reordering in Subitem Nos. 6 through 9, A through G, inclusive.

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.

This amendment also incorporates some changes in Subitem No. 9 because, as discussed in a telephone call between you and me on October 2, 2012, and other dates, authorizations for your customers may extend to other Sections in 10 CFR Part 35.

The changes made were listed in your letter dated August 30, 2012, and/or discussed and agreed upon in our October 2, 2012 call. If you have any comments or questions about this matter please contact me immediately at (630) 829-9841.

Also, as discussed with you in the October 2, 2012, call and on other dates, the request made in your letter dated September 13, 2012, concerning a higher activity generator, was not approved at this time because we have not received the additional information for labeling, etc. from you.

If or when you wish to revisit this request, please submit a written response containing the additional information about labeling higher activity generators, addressed to my attention as "additional information to control number 579080," ensure that it is signed by a senior management official and currently dated. These steps will greatly facilitate proper handling in our offices so that we may then continue our review.

If you have questions about these matters please contact me at 630-829-9841. My fax number is 630-515-1078 and my email address is colleen.casey@nrc.gov.

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."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

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.

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. 24-04206-05MD Docket No. 030-10801

Enclosure:

Amendment No. 41