

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

JUL 31 2012



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

Dear Mr. Hoffman:

Enclosed is Amendment No. 40 renewing 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 very carefully and be sure that you understand all conditions. Note that there have been many changes made in your license, including the addition of new standard conditions and the deletion and subsequent reordering in Subitem Nos. 6 through 9 A through I, 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 renews your license for a ten year period and your license will not expire until July 31, 2022.

We noted that a few remaining discrepancies and issues require clarification from your letter dated February 7, 2012. Please submit a written response within 30 days of the date of this letter (or contact me to make alternative arrangements) in order to resolve these matters.

Please address your response to my attention as "additional information to control number 575066," 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.

The following discrepancies and issues were noted with respect to your letter dated February 7, 2012:

- 1. Please clarify the correct address at which licensed material may be distributed from. Please see Condition No. 11 on your license and Condition No. 11 on the sample license in Appendix D to NUREG 1556, Vol. 12, "Consolidated Guidance**

About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution,” dated December 2000 that we referred you to in our conversation record dated November 1, 2011.

As needed, please refer to Appendix C; Table 8.2; Appendix D (for sample licenses); Appendix F; Appendix U; 10 CFR 32.72; 10 CFR 32.74; and 10 CFR 35.

- 2. The following issue is a holdover from our conversation record dated November 1, 2011, item 4, that was not addressed in your letter dated February 7, 2012. Please advise us as to how to disposition this request.**

Your letter dated April 28, 2011 also states, “As was the case for the current license (Condition 14) we hereby request the same or similar language regarding the submission of proposed changes in packaging, shielding labeling or package inserts. The rationale for this request is to avoid unnecessary delay in implementation of changes that do not adversely impact radiation safety or the size of the warning labels/symbols/wording.”

We reviewed Condition No. 14, which requires you to submit certain changes to the NRC for review. This appears to be a type of “flexibility” condition that I have not worked with before. In your renewal application, please explain specifically what types of “flexibility” you are seeking, provide at least one example, and justify and support why this license should not be amended prior to implementation of such changes.

- 3. Your letter dated February 7, 2012, was silent with respect to continuing authorization to distribute Sodium Iodohippurate and the Bristol-Myers Squibb Technelite Generators, which are listed as Subitem Nos. 6 – 9 D and J on Amendment No. 39. Since we were not directed to delete these authorizations, I assumed this was an oversight and continued these authorizations in the renewed license.**

In order for us to consider deleting these materials’ authorizations from this license, if that is what you intend to do, you must explicitly request that we do so and support such a request by amending the 21-04206-01 license and its corresponding authorizations, either concurrently with this license or prior to amending this license.

Please be reminded of the guidance contained in the copy of page 9-1, “Amendments and Renewals to a License,” from the NUREG 1556, Vol. 12 that we sent to you with our November 1, 2011, record. This excerpt states, in part, “It is the licensee’s obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place.”

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.

D. Hoffman

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 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. 40