COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 515-1078

CONVERSATION RECORD | TIME | DATE

Transmitted via PDF/scan/email to "Daniel.Hoffman@Covidien.com" **November 1, 2011**

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Daniel Hoffman, RSO for Mallinckrodt, LLC		314-654-7906

SUBJECT
License No.:24-04206-05MD Control No.: **575066**

SUMMARY

We have reviewed your letter dated April 28, 2011, requesting renewal of your byproduct materials license and find that we need additional information as follows:

In reviewing the renewal request letter dated April 28, 2011, signed by Mitzi Pennington, Site Director, we noted that the radiation safety program elements were mostly not addressed. It appeared that NUREG 1556, Vol. 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution", dated December 2000, was not used in the preparation of the renewal, rendering it mostly incomplete.

In order to complete your renewed license, to delete "old" documents from Condition 15 and simplify compliance with and understanding of your license, please respond in writing to the following issues.

Please contact me at (630) 829-9841 to arrange an alternate response date, if needed. My fax number is (630) 515-1078 and my email address is Colleen.Casey@nrc.gov.

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. Please include the names, functional identities, telephone numbers (no personal cellphone numbers, please) and fax numbers and/or email addresses of at least one or more persons who we can contact if questions with your response arise.

The following discrepancies and issues were noted with respect to your letter dated April 28, 2011:

1. **In order to prepare your renewal application and resubmit it in entirety, please use NUREG 1556, Vol. 12,"Consolidated Guidance About Materials Licenses:**

Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," December 2000, as it is intended for use by applicants, licensees, and NRC staff and is also available to Agreement States. The Abstract in this report states, "When published, this final report should be used in preparing manufacturing and distribution license applications. NRC staff will use this final report in reviewing these applications."

Full use of this document, and all of its sections that are appropriate for this license, for all of your licensing correspondence will greatly reduce your regulatory burden, simplify your license and enhance safety by providing for more comprehensive, updated safety procedures and a complete renewal application. This NUREG may be located on our website at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v12/sr1556v12.pdf

Specifically, 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.

Please also see the enclosed guidance for additional information and advice regarding renewal of licenses.

2. We noted that your letter dated April 28, 2011, stated "Also, please note that we have discontinued production of radiopharmaceuticals containing Xe-133, Cr-51 and P-32. "

However, your letter does not direct us to consider deleting these materials' authorizations from this license. In order for us to consider deleting these materials' authorizations from this license, if that is what you intend to do (and in our phone call today you stated that these materials have been permanently discontinued) 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.

This is because, when you say that you have discontinued production of certain materials, it appears to mean that you are referring to the 21-04206-01 manufacturing license, which this license is dependent upon for distribution purposes only.

In reviewing the 21-04206-01 license it did not appear that any changes to this license deleting authorizations for the production of the radiopharmaceuticals above had been requested or acted upon.

In our phone call today you indicated that, although these materials' production has been permanently discontinued, you believed that NRC does not require its

licensees to delete obsolete authorizations and keep licenses current. This is an apparent misunderstanding.

Please refer to the attached copy of page 9-1, "Amendments and Renewals to a License," from the NUREG 1556, Vol. 12 document above. 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 this matter please contact me at 630-829-9841.

3. It is not entirely clear to us why you submitted the product information summary, product package inserts and drawings for product shielding containers and components, as this information does not appear to provide equivalence to the information requested in NUREG 1556, Vol. 12. Perhaps this is also a misunderstanding.

4. 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 unique type of "flexibility" condition. 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.

Additional Guidance for Renewing an NRC License

Please note that using the NUREG 1556 series documents will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner.

In preparing future licensing correspondence please focus on providing the information requested in Appendix C to NUREG 1556, Volume 12. Follow the "Suggested Format.." provided in this Appendix and use the suggested responses and model procedure/appendix references whenever possible, appending descriptive information as appropriate. It is strongly advisable to read the corresponding text in the front of each NUREG to ensure a complete understanding of the commitments that you make.

Please do not submit resumes, curricula vitae, college transcripts, any personal, proprietary information, blueprint diagrams, or copies of blueprint diagram and any extraneous, prescriptive information and procedures, unless we specifically request it, which is unlikely.

If you are continuing authorization for an incumbent RSO and authorized users, please only provide their names and requested authorizations. Submission of an updated, current, "Delegation of Authority" for the incumbent RSO that is dated and signed by a senior management official, is recommended. It is not necessary to submit training and experience qualifications again for incumbent authorized staff.

If you must deviate from a model procedure or suggested response, it may be possible to simply indicate what the deviation is and still use the model procedure/ suggested response as a "basic" commitment. Descriptive information may be "recycled" from previous documents only so long as it is current, complete information equivalent to the model procedure (as appropriate) and does not contain extraneous material.

It is in your best interests to only provide those commitments, statements, representations and procedures, in a clear and explicit manner, that we require to issue your license. These documents will form the basis for the license in the last condition of the license, called the "tie-down" condition.

You will realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

In fact, the easiest way to prepare a renewal, for example, is to take a copy of NUREG 1556, Vol. 12, Appendix C, to your copy machine and copy it out directly, or print Appendix C from this document on our website at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v12/

It is imperative that you read the text in the front of the NUREG that corresponds to each section, in order to understand the commitments you are making or that you need to develop and submit. Simply fill in the checkmarks and blanks on the copied checklist, thereby making your license commitments, appending appropriate information as necessary.

Please do not re-type the checklist as errors and omissions may be introduced. As you need to append certain information or provide an alternative procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness.

If you wish, you may contact me at the telephone number above to discuss further on how best to go about generating the resubmittal of your renewal application. We would be happy to assist you as we are able.

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.

ACTION REQUIRED

Please submit the requested information within **30 calendar days (by December 1, 2011**) by referencing control number **575066** to facilitate proper handling. Please note that only one copy of your response is needed. A duplicate copy is no longer needed. Please address your written response to my attention at the above address.

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	November 1, 2011

9 AMENDMENTS AND RENEWALS TO A LICENSE

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. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a), 10 CFR 40.43(a), and 10 CFR 70.38(a)).

Applicants for license renewal and amendment must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request.
- Submit, in duplicate, either NRC Form 313 or a letter requesting amendment or renewal.
- Provide the license number.

For renewals, provide a complete and up-to-date application if many outdated documents are referenced or if there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or its Radiation Protection Program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

Using the suggested wording of responses and committing to use the model procedures in this report will expedite NRC's review.