



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352

JAN 25 2005

Ms. Carol Lentz
Radiation Safety Officer
Parke - Davis & Co.
2800 Plymouth Road
Ann Arbor, MI 48106-1047

Dear Ms. Lentz:

Enclosed is Amendment No. 57 renewing your NRC Material License No. 21-01443-06 in accordance with your request. Please note that some of the changes made to your license are printed in **bold** font. Your license has been issued for a six month term and will not expire until July 31, 2005.

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.

- A. This also refers to the telephone discussions between you and me on January 24, 2005, and January 25, 2005, concerning your renewed license. During my review of your renewal letter dated July 26, 2005, I noted that the renewal request had not been prepared in accordance with NUREG 1556, Vol. 7, in that only NUREG 1556, Vol. 11 was apparently used. Full use of both of these documents would have greatly reduced your regulatory burden and enhanced safety by providing for more comprehensive, updated safety procedures and a complete renewal application.

As your letter dated July 26, 2004, was incomplete in several key respects and the Enclosure 4 to your letter contained many extraneous details, I agreed to renew your license for six months by continuing your currently licensed documents in Condition No. 23. You agreed to resubmit a renewal application in entirety prior to the expiration of the license. Please address your renewal request to my attention and reference control number 313588 to facilitate proper handling.

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 your revised renewal request please focus on providing the information requested in Appendix C to NUREG 1556, Volumes 7 and 11. 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 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, and any extraneous, detailed information and procedures.

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.

Further, it appears that Enclosure 4 to your letter dated July 26, 2004, is styled after a "Radiation Safety Manual (RSM)" type of document, which is inappropriate for the renewal of your license. This is because RSM documents contain prescriptive, restrictive and extraneous details that, if incorporated into your license, greatly increases your regulatory burden. However, these details do not provide the relevant information that we need in order to renew the license. It would probably be best if you did not recycle information directly from the letter dated July 26, 2004, Enclosure 4. Enclosure 4 has been excluded from this renewal in License Condition No. 23.

In fact, the easiest way to prepare your renewal is to take copies of NUREG 1556, Vols. 7 and 11, Appendix C to your copy machine and copy it out directly. Read the text in the front of the NUREG that corresponds to each section and simply fill in the checkmarks and blanks on the copied checklist, thereby making your license commitments. Please do not re-type the checklist as errors and omissions may be introduced. If 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 have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

- B. Specific information concerning the letter dated July 26, 2004, and deficiencies identified include, but may not be limited to, the following:
1. I could not read the organization chart provided as the copy was poor and the print font too small to decipher. It also appeared to provide information that I did not need. Please submit "chain of command" organizational information pertaining to senior management and the Radiation Safety Office. NUREG 1556, Vol. 11, section 8.7.1 may be of assistance to you in preparing your response.
 2. Your application was silent with respect to Subitem Nos. 6., 7., 8., and 9. U. I continued authorization for this material as I assumed this was an oversight. If you wish to delete this authorization please explicitly direct us to do so in your revised

renewal and support your request accordingly.

3. Please submit a statement delineating your duties as RSO. NUREG 1556, Vol. 11, Item 8.7.3 and NUREG 1556, Vol. 7, Item 8.7.1 and Appendix I may be helpful to you in preparing your response.
4. Please confirm that you, as the Radiation Safety Officer, will evaluate applications for authorized users, authorized uses and areas of use for licensed materials.
5. Please submit the criteria you will use to evaluate and approve/disapprove new users and uses of byproduct material. The training and experience described in 10 CFR 33.15(b), which applies primarily to Type C broad scope licensee, is a good guideline for Type B and even Type A broad scope licensees as well.
6. Your letter dated July 26, 2004, failed to address certain elements in the proposed training program, including qualification of the instructors, method of training and method for assessing the success of the training. The training program for individuals working in or frequenting restricted areas should address all of the information in Item 8.8 in both NUREG 1556, Volumes 7 and 11 and Appendix J in NUREG 1556, Vol. 7.
7. The description and diagrams of your facilities and equipment in the letter dated July 26, 2004, were incomplete. Please address all appropriate information in NUREG 1556, Vol. 11, Item 8.9.9 and Appendices K and L and NUREG 1556, Vol. 7, Item 8.9.9 and Appendix K.
8. Please describe your proposed audit program, including the specification and justification of audit frequency. Please address all appropriate information in NUREG 1556, Vol. 11, Item 8.10.1 and Appendix M and NUREG 1556, Vol. 7, Item 8.10.1 and Appendix L.
9. Please describe your radiation monitoring instrumentation and address all appropriate information in NUREG 1556, Vol. 11, Item 8.10.2 and Appendix O and NUREG 1556, Vol. 7, Item 8.10.2 and Appendix M.
10. Please describe your administrative procedures to assure control of procurement and use of byproduct material. Please define what a "source custodian" is, as the term is used in your letter dated July 26, 2004. Please note that it is expected that your inventory control should be an ongoing system, updated essentially on a daily basis. Please explain and justify if your inventory system will be updated less frequently than daily.

Please address all appropriate information in NUREG 1556, Vol. 11, Item 8.10.3 and Appendix P and NUREG 1556, Vol. 7, Item 8.10.3 and Appendix N.
11. Please describe your use of byproduct materials in animals. Please address all appropriate information in NUREG 1556, Vol. 7, Appendix H.
12. Please describe your waste management procedures in more specific terms. Please

address all appropriate information in NUREG 1556, Vol. 11, Item 8.11 and Appendix V and NUREG 1556, Vol. 7, Item 8.11 and Appendix T.

- C. Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:
1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
 2. Notify NRC, in writing, within 30 days:
 - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license changes.
 3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.
 4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the address or addresses of use identified in the license application or on the license; or
 - d. Change ownership of your organization.
 5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and

initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

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. 21-01443-06
Docket No. 030-04794

Enclosure:

Amendment No. 57