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

JAN 3 1 2005

Mr. Jerome W. Staiger
Radiation Safety Officer
University of Minnesota
W-168 Boynton Health Service
Minneapolis, MN 55455

Dear Mr. Staiger:

Enclosed is Amendment No. 11 renewing your NRC Material License No. 22-00187-54 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 ten-year term and will not expire until January 31, 2015.

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. During my review of your renewal letter dated August 4, 2004, I noted that the renewal request had not been prepared in accordance with NUREG 1556, Vol. 6, although the abstract in NUREG 1556, Vol. 6 states, "This final report should be used in preparing Part 36 Irradiator License Applications. NRC staff will use this final report in reviewing these applications."

Full use of this document 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 August 4, 2004, was incomplete in many respects I renewed your license by continuing your currently licensed document, the letter dated June 9, 1994, in Condition No. 28.

For future reference, 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 6. 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 <u>not</u> 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.

In fact, the easiest way to prepare a renewal, for example, is to take a copy of NUREG 1556, Vol. 6, 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.

B. Please note that I was unable to approve Elizabeth A. McNiel, DVM and Kari L. Anderson, DVM as irradiator operators at this time because the information submitted in your letter dated August 4, 2004, was insufficient to complete my review. If you wish to pursue these requests please provide the information requested below, addressed to my attention and reference control number 313620 to facilitate proper handling. I will then continue my review.

Drs. McNiel and Anderson were not approved as irradiator operators because their training and experience did not appear to meet the recommended training and experience levels described in NUREG 1556, Vol. 6, section 8.8.1 and Appendix G. Please submit brief, concise training and experience descriptions for each doctor that clearly meets the recommended training and experience levels described in NUREG 1556, Vol. 6, section 8.8.1 and Appendix G. As noted above, please do not submit resumes, curricula vitae, college transcripts, any personal, proprietary information, and any extraneous, detailed information.

Please refer to NUREG 1556, Vol. 6, and 10 CFR Part 36 if you have questions about these matters. 10 CFR 36 and NUREG 1556, Vol. 6 are available on our website at http://www.nrc.gov. Then click on the "Nuclear Materials" toolbar key and the "Industrial Users of Nuclear Materials" option on the Quick List. Then select "Irradiators," "Toolkit" and "Guidance" or "Regulations," to find either NUREG 1556, Vol. 6 or 10 CFR Part 36, respectively.

If you have further questions concerning these matters please contact me at (630) 829-9841

or (800) 522-3025.

C. I restored Condition No. 27, which exempts this license from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits of 10 CFR 30.35(d) for the purpose of source changes only.

D. 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

Colleen Carol Casey
Materials Licensing Branch

License No. 22-00187-54
Docket No. 030-19162

Enclosure:

Amendment No. 11