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

JUL 2 5 2005

J. Thomas Payne, Ph.D.
Radiation Safety Officer
Abbott Northwestern Hospital
800 E.28th Street at Chicago
Minneapolis, MN 55407

Dear Dr. Payne:

Enclosed is Amendment No. 61 renewing your NRC Material License No. 22-04588-01 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 January 31, 2006.

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 discussion between you and me on July 22, 2005, regarding your renewed license. This also refers to the voicemail message I left for you on July 22, 2005, and your subsequent voicemail message left for me on July 25, 2005, concerning the confirmation in our understanding of the change in term of this renewal from a one year to a six month term.

During my review of your renewal application and letter dated January 24, 2005, I noted that the renewal request had not been fully prepared in accordance with NUREG 1556, Vol. 7, or NUREG 1556, Vol. 9, in that only NUREG 1556, Vol. 11 was apparently used to a significant degree.

Full use of all three 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 application and letter dated January 24, 2005, were incomplete in several key respects and 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 314131 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, 9 (Rev. 1) and 11. Follow the

"Suggested Format.." provided in each 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, procedures and retyped sections from advisory text in the NUREG-series documents.

It is also not necessary to resubmit training and experience information for incumbent staff and users named on the license, whose licensed functions are not changing. You may simply reference each appropriate person's position and name and state that his/her training and experience documents are already on file in the license.

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" directly from previous documents only to the extent that 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 your renewal is to take copies of NUREG 1556, Vols. 7, 9 (Rev. 1) and 11 to your copy machine and copy each Appendix C section directly.

Read the text in the front of the NUREG that corresponds to each item in each Appendix C section and simply fill in the checkmarks and blanks on the copied checklists, thereby making your license commitments.

As noted above, please do not re-type the checklists 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.

Also, please check your current license to ensure that you have not omitted anything that you wish to continue authorization for, such as locations of use, line items, etc. On the other hand, if you wish to delete an authorization that you currently have, be sure to specifically request the deletion, state why, and support each request with appropriate information that

justifies granting the request (such as leak tests, final surveys, acknowledgments of receipt from vendors, etc.)

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

B. Specific information concerning the application and letter dated January 24, 2005, and deficiencies identified include the following:

1. Your application appears to place your high dose rate remote (HDR) afterloading brachytherapy device in a room that does not match the currently licensed location. The current license authorizes the HDR device in Room 15002 at the main hospital address; your application places it in Rooms 1928 and 1930. Please contact me at the above telephone numbers **immediately** if your HDR device is being used in a room that NRC has not reviewed and approved, as additional information will need to be submitted promptly to address this situation. Please explain this discrepancy otherwise.

2. Your application was nearly silent with respect to many of the specific radiation safety program elements required for medical use (NUREG 1556, Vol. 9, Rev.1) and research and development (NUREG 1556, Vol. 7). Please ensure that each of these elements are addressed and supported completely in your resubmittal, especially HDR procedures, as requested. Certain specific information below will also address some, but not all, of these elements, as "carry-over" from the renewal application.

3. Note that at this time I added a specific authorization for depleted uranium as shielding in generators as Subitem No. 6.J.

4. I also deleted line item authorizations, as they appeared on Amendment No. 60, for Subitem No. 6.H., because it is included in 10 CFR 35.500 (Subitem No. 6.E.), and for Subitem Nos. 6.I. and 6.L., which are covered by the authorization in 10 CFR 35.65. The line items were re-ordered somewhat as a result of these changes.

5. In License Condition 10.D. I deleted reference to the gadolinium-153 use because it is already included in the authorization for materials in 10 CFR 35.500.

6. I modified Condition No. 13 to include radioactive materials with a half-life of up to 120 days, as per Regulatory Issue Summary RIS 2004-017.

7. I updated Condition No. 12.A through D, inclusive, Condition No. 14.D, and Condition No. 21 to reflect current NRC licensing policy.

8. Please evaluate Condition No. 15, which I updated for revised 10 CFR Part 35. It was not clear from your application whether you intended to continue this exemption or not. If you do wish to continue this Condition, please so state explicitly and support and justify your request with appropriate information equivalent to the letters dated November 9, 1994, January 27, 1995, and March 20, 1996. If you no longer wish to continue this Condition, please advise me to delete it in your response.

9. Please check all currently licensed locations of use in Condition No. 10, especially 10.C, and correlate each in your response with a clear description of what modalities are being used at each location and submit appropriate diagrams. It was not clear from your application that all currently licensed locations of use were adequately addressed. In particular, it appeared that the currently licensed location at 920 East 28th Street, Minneapolis, Minnesota was not mentioned in your renewal application. Further, your application mentions "Hickock Research Lab - 4M 109 Sears Building," but no address is given. Please respond carefully and completely to this item.

10. Please submit a signed delegation of authority statement for the Radiation Safety Officer (RSO), as there are two versions in your application, both of which were unsigned by the RSO and management.

11. Please provide the radionuclides, manufacturer's names and model numbers for all sealed sources you possess or intend to possess under 10 CFR 35.400 and 35.500. Please note that the information you provide to us must match up exactly with the manufacturer - provided data in the Sealed Source and Device Registry, available from the manufacturers.

    It may be necessary for you to contact these vendors to obtain current SSDR certificates for each of the sealed sources you wish to be authorized for, as some of the older vendors have merged, gone out of business or changed their SSDR certificates substantially since the original approval dates.

    Please contact me at one of the telephone numbers above if you need assistance. You may also refer to NUREG 1556, Vol. 9, Final, Section 8.5, Item 5 and Table C.2, Items 5 and 6.

    When my review of your response is final, I will authorize the appropriate radionuclides, manufacturers, and model numbers for the materials in 10 CFR 35.400 and 35.500 that you wish to use.

    Note that the inventory of sealed sources submitted in your application will not suffice for this purpose as it contains insufficient, incomplete and inappropriate information to evaluate your request for sealed sources in 10 CFR 35.400 and 35.500.

12. Please submit the criteria that will be used by the Radiation Safety Committee and the RSO 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 non-human use.

    Please confirm that 10 CFR 35 and corresponding sections and preceptor statements provided in NUREG 1556, Vol. 9, Rev. 1, or the equivalent, will be used to evaluate and approve/disapprove new users and uses of byproduct material for human use, Authorized Medical Physicists, etc.

13. Your application failed to address certain elements in the proposed training program,

including the identities of groups of workers to be trained, topics to be covered, method of training and method for assessing the success of the training. Please submit this information. In the alternative, please identify the model training program described in the appropriate base NUREG corresponding to your particular types of licensed programs (Vols. 7 and 9, Rev. 1) and submit a statement that these training programs will be implemented.

In addition please confirm that workers will be trained when the license and/or regulatory requirements that affect them change.

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.

14. Your application stated that, while no animal use is currently being practiced, you want to have authorization for animal use included in the license. Please be advised that, to include animal use in your license, it will be necessary for you to submit the information in Appendix H, NUREG 1556 Vol. 7 at this time. Please describe your expected use of byproduct materials in animals. Please address all appropriate information in NUREG 1556, Vol. 7, Appendix H.

15. The description and diagrams of your facilities and equipment in your application were incomplete, partially because of the discrepancies noted above with Condition No. 10. Please address all appropriate information in NUREG 1556, Vol. 11, Item 8.9.9 and Appendix C, Item 9, and Appendices K and L, and NUREG 1556, Vol. 7, Item 8.9.9 and Appendix K.

Your application states that you will use a laboratory classification scheme based on Appendix K but that yours will "differ." Please state specifically what these differences will be. Please provide sample diagrams for each type of laboratory classification you will have.

Please describe the minimum criteria that each type of laboratory classification and/or area of use, especially special application facilities, will be held to for review by your Radiation Safety Committee. Please describe your procedures for control, review and approval of significant facilities or equipment modifications.

16. Please describe your proposed audit program, including the specification and justification of audit frequency, based upon the type of laboratory classification, including medical uses. The audit's scope and frequency should correlate with the laboratory classification and potential hazards in each type of lab.

Please describe the mechanisms used by executive management to ensure that adequate oversight of the program is exercised.

In addition, since you are renewing your license, describe the RSC's involvement in these oversight mechanisms. 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.

Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC - approved permits and good health physics practices.

Please confirm that progressive enforcement actions will be employed for those laboratories and staff who present compliance problems.

17. Please describe your radiation monitoring instrumentation and address all appropriate information in NUREG 1556, Vol. 11, Item 8.10.2, and Appendix C, Item 10; NUREG 1556, Vol. 7, Item 8.10.2 and Appendix M and NUREG 1556, Vol. 9.1, Appendix C, Item 9, "Radiation Monitoring Instruments."

Please note that I excluded Alternate Method 2 from your application in Condition No. 23 because I am concerned that this method may introduce an additive error potential to the calibration process described. In the alternative, if you wish to use Alternate Method 2, please confirm that instruments calibrated in this manner will not be used to perform surveys required by 10 CFR 35,10 CFR 20 or 10 CFR 71. Please call me to discuss this matter further if you wish.

18. Please describe your administrative procedures to assure control of procurement and use of byproduct material and specify whether the RSO approves of each order of licensed material prior to the order being placed to ensure that possession limits are not exceeded and that decommissioning financial assurance is not required to be executed first.

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.

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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The enclosed license document is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability.

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. 22-04588-01
Docket No. 030-02223

Enclosure:

Amendment No. 61