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

APR 2 9 2005

Christopher A. Jackson, M.D.
Radiation Safety Officer
HealthEast - St. Joseph's Hospital
69 West Exchange Street
St. Paul, MN 55102

Dear Dr. Jackson:

Enclosed is Amendment No. 66 to your NRC Material License No. 22-01448-01 in accordance with your request. Your license has been issued for a ten year term and will not expire until April 30, 2015. Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully, as many changes and reformatting have occurred, and 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. If you have any questions concerning this renewal please contact me at either (630) 829-9841 or (800) 522-3025.

A. During my review of your renewal application dated October 21, 2004, and the letter dated October 20, 2004, I noted that the aggregate renewal request had not been completely prepared in accordance with NUREG 1556, Vol. 9 and the appropriate guidance for emerging technologies licensed pursuant to 10 CFR 35.1000, available on our website. Full use of all of this information would have greatly reduced your regulatory burden and enhanced safety by providing for more comprehensive, updated safety procedures and a complete renewal application.

NUREG 1556, Vol. 9 is available by accessing our website at:

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

The medical licensing information is also available at:

http://www.nrc.gov/materials/medical.html

If you need assistance locating these documents on our website please contact me as noted above.

As your application dated October 21, 2004, and the letter dated October 20, 2004, was incomplete in several key respects I renewed your license by continuing your currently licensed documents in Condition No. 17. I also spoke briefly about this with Richard Hanson in a telephone conversation on April 29, 2005.

As it is in your best interests to replace the old documents in Condition No. 17 that are dated prior to October 21, 2004, with current and complete commitments, please address the information described below in section B of this letter. To clarify and resolve the items in question, which will complete your license, a written response should be submitted within 30 days of the date of this letter. If additional time is needed to prepare

a response, please contact me as noted above. Your response should be addressed to my attention and refer to control number 313855 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 response and especially all future licensing correspondence please focus on providing the information requested in Appendix C to NUREG 1556, Volume 9, entitled "Suggested Format for providing the information requested in items 5 through 11 on NRC Form 313."

It is recommended that you 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.

Some general suggestions include not submitting 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 your future licensing correspondence is to take a copy of Appendix C to NUREG 1556, Volume 9, entitled "Suggested Format for Providing the Information Requested in Items 5 through 11 on NRC Form 313" to your copy machine and copy it directly (or the relevant sections therein).

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, such as responses to emerging technology guidance, or provide an alternative procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness.

For the sake of licensing economy, I included a review of your request dated January 13, 2005, (under control number 314189) to add Mark A. Palmer, M.D. to your license as an authorized user. Dr. Palmer was not approved as an authorized user at this time

because his training and experience did not appear to meet regulatory requirements. Additional information concerning this request is address in section C of this letter below.

B. Specific discrepancies concerning the application dated October 21, 2004, and the letter dated October 20, 2004, ("renewal correspondence"), include the following:

1. Your renewal correspondence was silent with respect to continued authorization for: the two satellite locations of use listed on Condition No. 10.B. of the license; depleted uranium shielding for the linear accelerator; materials in 10 CFR 35.400 other than strontium-90 eye applicator and cesium-137 inventory (i.e., iodine-125, iridium-192, etc.)

   As I assumed these were oversights I continued all of these authorizations as they appeared on Amendment No. 65, prior to the renewal. Note that the authorization for materials in 10 CFR 35.400 in Subitem No. 6.J. is intended to be a temporary authorization. Please submit the manufacturer's names and model nos. of the other radionuclide's sealed sources you wish to be authorized for.

   If you wish to delete the authorizations for depleted uranium and the other two satellite locations of use please explicitly direct us to do so in your response and support your request accordingly. If you require additional information on how to support such requests contact me as noted above.

   If you wish to retain these authorizations please submit explicit requests to continue each authorization and support each request in accordance with the guidance in NUREG 1556, Vol. 9.

2. Your renewal correspondence requested continued authorization for use of the Novoste intravascular brachytherapy devices but failed to provide appropriate commitments and procedures in support of this request. I continued authorization for this material by relying on supporting information contained in Condition No. 17 dated prior to October 21, 2004.

   If you wish to continue this authorization please update and resubmit appropriate commitments and procedures to support this request and respond to the guidance on our website for emerging technologies. A copy of this guidance is attached to this letter.

   If you wish to delete this authorization, please so state and support your request appropriately. If you require additional information on how to support such a request contact me as noted above.

3. Certain discrepancies were noted with respect to your requested authorized users as follows:

   a. Your renewal correspondence requested the expansion of Dr. Carl Bretzke's authorization to include materials in 10 CFR 35.300. However, no information supporting this request was included and the additional authorization was not

approved. If you wish to pursue this expanded authorization please submit information demonstrating that Dr. Bretzke meets the training and experience requirements in 10 CFR 35.390 or 35.930 and 35.59, as appropriate.

b. I corrected Dr. Timothy V. Meyers' name to reflect the correct spelling of "Meyers," instead of "Myers," as it appeared previously. This was done in accordance with your renewal correspondence.

c. Dr. Joseph J. Baraga's authorization in your renewal correspondence did not include his previous authorization for materials in 10 CFR 35.300. I considered this an oversight and continued his authorization for materials in 10 CFR 35.300 anyhow. Please advise me if you wish to revise the scope of Dr. Baraga's authorization in your response.

d. I corrected Dr. Vichaivood Lienswangwong's name to reflect the correct spelling of "Lienswangwong," instead of "Liengswangwong," as it appeared previously. This was done in accordance with your renewal correspondence.

e. The authorization for one of your new proposed authorized users, Dr. Alexandra Muschenheim, was requested differently than as her authorization appears on the referenced license no. 22-24441-01. On the referenced license, Dr. Muschenheim's authorization for materials in 10 CFR 35.300 excludes hyperthyroidism treatments. Your request excluded thyroid carcinoma treatment instead of hyperthyroidism treatments. I prepared the license in accordance with the version on the referenced license.

4. Your renewal correspondence did not describe your instrumentation. Please submit a description of the instrumentation that will be used to perform required surveys. Appendix K in NUREG 1556, Vol. 9, may assist you in preparing your response.

C. Dr. Mark A. Palmer was not approved as an authorized user for the use of materials in 10 CFR 35.300 and 35.400 because his application and preceptor statement did not adequately support his requests for these types of use in order to completely meet the requirements in 10 CFR 35.390 or 35.930 and 35.490 or 35.940.

1. Dr. Palmer's application and preceptor statement ("documents") indicates that he was certified in Radiation Oncology by an unnamed specialty board in June 2004. However, no certificate was provided to support this assertion.

   I checked the American Board of Medical Specialties website and found that Dr. Palmer's certification is in Internal Medicine only. Please explain this discrepancy and provide a copy of the certificate showing that Dr. Palmer was certified in June 2004 by a medical specialty board that the Commission recognizes in the regulations cited above.

2. Dr. Palmer's documents show he completed a total of 111 hours of didactic training in three of five topical training areas. This appears to be insufficient to meet the requirements in:

(a) 10 CFR 35.930(b)(1)(iii), 35.390(b)(1)(i)©), 35.940(b)(1)(iii) and 35.490(b)(1)©) for lack of didactic training in mathematics pertaining to the use and measurement of radioactivity;

(b) 10 CFR 35.390(b)(1)(i)(D) for lack of didactic training in chemistry of byproduct material for medical use; and,

(c) 10 CFR 35.940(b)(1) and 35.490(b)(1)((l), as 200 hours of didactic training are required and only 111 hours were received.

3. Dr. Palmer claimed no supervised clinical training for the use of materials in 10 CFR 35.300, contrary to the requirements in 10 CFR 35.930(b)(2) and 35.390(b)(ii). Please submit a revised, currently signed and dated preceptor statement when Dr. Palmer has completed the required supervised clinical training.

4. Dr. Palmer's preceptor statement in section 5b refers to "I131 prostate impl...plaques..." I took this to mean that he was referring to iodine-131 prostate implants and plaques. However, prostate implants and eye plaque treatments are performed using iodine-125 sources, not iodine-131. Please explain this discrepancy and submit a revised, currently signed and dated preceptor statement correcting these errors.

5. Dr. Palmer's preceptor statement indicates he completed 500 hours of supervised clinical cases but insufficient details are provided to evaluate his work against 10 CFR 35.940(b)(2), 35.940(b)(3), 35.490(b)(ii) and 35.490(b)(ii)(2). Please submit a revised, currently signed and dated preceptor statement providing the specific details requested.

6. It is not clear who served as Dr. Palmer's preceptor as five names of physicians appear to be provided in sections 5a and 5b but the handwritten names are difficult to decipher. The signatures in sections 9 and 12 are also difficult to decipher and sections 11a and 11b were completed incorrectly. Please submit a revised, currently signed, dated and legible preceptor statement providing the requested information. Please refer to Appendices B, D and E for assistance completing preceptor forms correctly.

7. I could not verify the identities and credentials of Dr. Palmer's preceptors, based upon the information given on the preceptor form. The referenced license for the preceptors is for the University of Minnesota, a broad scope license that does not include the names of specific authorized users. The Radiation Safety Committee for that license evaluates and approves/disapproves of authorized users internally.

   Please submit a letter currently signed and dated by either the RSO or the RSC Chairperson for the University of Minnesota attesting that Dr. Palmer's preceptors (please name them individually) were authorized users for materials in 10 CFR 35.300 and 35.400 under license no. 22-00187-46, during the specific, designated time frames when Dr. Palmer was trained.

   Please do <u>not</u> submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers,

dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

8. 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."

D. 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.

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.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 22-01448-01
Docket No. 030-02200

Enclosures:

1. Amendment No. 66
2. Novoste website guidance