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

FEB 2 3 2006

Andrea D. Browne, Ph.D.
Radiation Safety Officer
Community Hospitals of Indiana
1500 North Ritter Avenue
Indianapolis, IN 46219

Dear Dr. Browne:

Enclosed is Amendment No. 69 to your NRC Material License No. 13-06009-01, in response to your request by two letters both dated November 17, 2005. The first involved a request for release for unrestricted access and use of your former location of the blood irradiator. This request is being granted based on the information submitted which included a diagram of the old facility and its location in your facility, along with a close-out survey of the facility confirming the absence of remaining activity and a leak test confirming the non-leaking status of the sealed source and confirmation that you have never possessed any leaking sealed sources in that facility, based on routine leak test data.

The second letter dated November 17, 2005, requested addition to the license of new authorized users and new authorized medical physicists. Please note that we authorized Scott L. Ackley, M.D., Peter G. Garrett, M.D. and Alexander M. Yeh, M.D. for uses of licensed material under 10 CFR 35. 300 and 35.400, as requested, on the basis of their being already named as users for these materials on another license. However, we could not at this time authorize any of these doctors for the requested use of Iridium-192 in a high dose rate afterloading device because no evidence of training/experience was provided for the requested use. As of October 24, 2005, the regulations governing the training/experience requirements for use of remote afterloader units is described in 10 CFR 35.690. Except for an experienced authorized user, as provided for in 10 CFR 35.57, the regulations describe two paths of acceptable training for use of remote afterloader units as follows:

The first involves certification by a medical specialty board as described in 10 CFR 35.690(a), recognized by the NRC under 10 CFR Part 35 (none recognized as of February 23, 2006) and receipt of training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as described in 10 CFR 35.960 (c), and written attestation (signed by a preceptor authorized user who meets the applicable requirements in 10 CFR 35.690) that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (c) of 10 CFR 35.690.

The second path involves completion of a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes 200 hours of classroom and laboratory training and 500 hours of work experience under the supervision of an authorized user as described in 10 CFR 35.690 (b)(1) (i) and (ii). Additional requirements include completion of 3 years of supervised clinical experience in radiation therapy under an authorized user, training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought and written attestation that the individual has satisfactorily completed the requirements as described in paragraphs (b)(1) and (b)(2) and (c) of

10 CFR 35.690. An NRC Form 313A, "MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION", must be used when providing the above information for each proposed authorized user.

Also, please note that we have reviewed the NRC Form 313A submitted, documenting training, experience and Preceptor Attestation, requesting the designation on the subject license, of two individuals, Duan Qiang (David) Wang and Ana Mihail, as Authorized Medical Physicists (AMP) for iridium-192 in High Dose Rate (HDR) Remote Afterloading Brachytherapy devices. However, due to deficiencies in the qualifications and/or information provided, as described below, we could not authorize either individual as an AMP at this time.

For Ana Mihail, the following additional or modified information needs to be addressed:

NRC Form 313A Item 6a, "Work or Practical Experience with Radiation" should reflect the requirements in 10 CFR 35.51 (b)(1), including, sealed source leak tests and inventories, decay corrections, full calibrations and spot checks, and radiation surveys.

NRC Form 313A Item 6c, "Training for Sections 35.51(c)" should include hands on device operation, safety procedures, clinical use, and operation of treatment planning system, either provided by the vendor or by an AMP authorized for the type of use for which the individual is seeking authorization.

NRC Form 313A Item 9, "Medical Physicist – One-Year Full-Time Training/Work Experience", The final "blank" in this section, as submitted, did not specify the "use or device", i.e. 35.600 or Ir-192 HDR device.

NRC Form 313A Item 10 "Supervising Individual – Identification and Qualifications", The final "blank" in sub-item C, for medical uses in Part 35, Section(s) needs to reflect sealed source therapy in a remote afterloader unit, i.e. 600, not radiopharmaceutical usage as represented by 200, 390, and 396. **Also, please note that Item 10 needs to be addressed for each supervising individual (including Al Foster, Joe Butts and Matthew Walters).**

NRC Form 313A Item 11a, "Preceptor Attestation", neither blank was filled in to attest that the individual named in Item 1 has satisfactorily completed the requirewments in Part 35, Section(s) and Paragraph(s) (it appears this should reference 35.51 (b)) as documented in section(s) (it appears this should reference 6a, 6b, 7 and 9) of this form.

NRC Form 313A Item 11b, "Preceptor Attestation", while the box was checked for 35.51(c), neither succeeding blank was filled in. It would appear that these should state respectively, for " Ir-192 HDR therapy" types of use, as documented in sections "6c." of this form

NRC Form 313A Item 11d, "Preceptor Attestation", the box should be checked confirming that the preceptor is an AMP (reference Licence Condition 12.D. of License No. 13-06009-01). The blank in the next line, to identify byproduct material uses (or units), should, it appears, reference "Ir-192 HDR therapy" or "35.600".

For Duan Qiang (David) Wang , the following additional or modified information needs to be addressed:

NRC Form 313A Item 6a, "Work or Practical Experience with Radiation", for the last two items "External beam daily, quarterly and annually QA" and "2D/3D and IMRT treatment planning and QA procedures", please provide the dates of this work or practical experience rather than state "in the past five years".

NRC Form 313A Item 7, "Formal Training", please provide the "Name of organization that approved the Program (e.g. Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490).

NRC Form 313A Item 9, "Medical Physicist – One-Year Full-Time Training/Work Experience", after the second box checked, both blanks for specifying "use or device" appear to incorrectly reference radiopharmaceutical usage rather than referencing the HDR device or the regulations addressing it, e.g. 35.600.

NRC Form 313A Item 10 "Supervising Individual – Identification and Qualifications", The final "blank" in sub-item C, for medical uses in Part 35, Section(s) needs to reflect sealed source therapy in a remote afterloader unit, i.e. 600, not radiopharmaceutical usage as represented by 200, 390, and 396.

NRC Form 313A Item 11d, "Preceptor Attestation", the box should be checked confirming that the preceptor is an AMP (reference Licence Condition 12.D. of License No. 13-06009-01). The blank in the next line, to identify byproduct material uses (or units), should, it appears, reference "Ir-192 HDR therapy" or "35.600".

If you wish to pursue the users and uses that were not granted at this time, please provide the requested information and we will continue our review at that time.

Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully 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.

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. The signatory for an application for medical use must be the licensee's management, as required by 10 CFR 35.12(a).

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.

This letter and the enclosed license document are exempt from public disclosure in accordance with 10 CFR 2.390, because their disclosure to unauthorized individuals could present a security vulnerability.

Sincerely,

Loren J. Hueter

Loren J. Hueter
Materials Licensing Branch

License No. 13-06009-01
Docket No. 030-01625

Enclosure: Amendment No. 69