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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. STE 210
LISLE, IL 60532-4352

FEB 13 2019

Liang (Larry) Wang, M.S.
Radiation Safety Officer
Elkhart General Hospital
P. O. Box 1329
Elkhart, IN 46515-1111

Dear Mr. Wang:

Enclosed is Amendment No.61 to your NRC Material License No. 13-18879-01 in accordance with your request.

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.

If you have any questions concerning this amendment, or the additional information requested below, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078 and my email address is colleen.casey@nrc.gov.

Please note that we are also sending a courtesy copy of this letter only to Katie Shively, Director of Radiation Oncology Services.

We are also returning to you a plastic report cover with five insert tab pages but no information whatsoever. This item was included in the original envelope that transmitted your letter dated November 14, 2018. We assumed that sending this was in error so we are returning it to you.

In correspondence dated November 14, 2018, December 13, 2018 and February 11, 2019, you indicated that you wished to release the storage room for your former high dose rate (HDR) remote afterloading brachytherapy device at the 600 East Boulevard, Elkhart, Indiana location from the license for unrestricted use.

The NRC staff has reviewed your final status surveys. Based on its review, the staff has concluded that all licensable radioactive material has been removed from this location of use and that residual radioactive material attributable to licensed activities does not exceed current NRC criteria.

Based on these conclusions no further remediation or actions with respect to NRC regulated material is required for this area of use and your former storage room for the HDR device is suitable for unrestricted use.

Since this amendment resulted in the removal of your HDR authorization, we also had change affected sections in your license. Specifically, we deleted authorization completely for your authorized medical physicists, Daniel J. Archambeault, M.S. and Lianag (Larry) Q. Wang, M.S.; and for authorized users Lauren C. Das, M.D., David A. Hornback, M.D. and Samuel D. McGrath, M.D.

The enclosed document contains sensitive security-related information. When separated from this cover letter this letter is uncontrolled.

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We deleted authorization for the use of the HDR device, but other authorization(s) remain on the license, for Joel N. Cohen, M.D., Russell F. Johnson, M.D., Brion B. Shin, M.D., Nguyen Binh Tran, M.D. and Chester Wilson, M.D.

We deleted authorized users Daniel A. Boll, M.D., Nazar Golewale, M.D., Benjamin Jon Moreno, M.D. and T. E. Seiffert, M.D., as requested in your letter dated December 19, 2018.

We added authorized users Syed I. Ali, M.D., Mark Allen Crain, D.O., Stephen Joowhan Kim, M.D. and Naila Qazi, M.D., as requested in your letter dated December 19, 2018.

This also refers to the telephone discussion between you and Katie Shively, Director of Radiation Oncology Services for your hospital, and me on February 7, 2019. We discussed my letter to you requesting additional information dated November 29, 2018, and your first response letter dated December 13, 2018.

In our discussion, I specifically requested that you refrain from sending us extraneous and duplicate documents, as there were several of these in your letter dated December 13, 2018.

However, in your second response letter dated February 11, 2019, 3 more extraneous and duplicate documents were enclosed, consisting of the acknowledgment of receipt from Alpha-Omega Services, Inc. dated September 3, 2017, and the licenses for Varian Medical Systems, Inc. and Alpha-Omega Services, Inc.

These same documents were enclosed with your letter dated December 13, 2018, and I did not ask for an additional copy of them as one copy was sufficient.

I hope that this helps you determine the appropriate documentation to submit in the future, especially with respect to the cesium-137 sources that you are in the process of preparing a written response to us in order to remove this authorization from your license.

If you have any questions about such matters, please email me (usually quickest) and/or call me, as shown above.

In the latter part of the review process for this amendment, you told us that completion of the amendment was needed for a construction project.

You had not included this information in your initial correspondence and telephone calls with us. In order to assist you in the future if you should experience an unforeseen need for an "expedited" amendment request, the following information is offered. This is not official guidance; it is language that I have developed and used many times over the years in similar situations.

"Expedite" Requests:

As a medical licensees, please take special note of the definitions in 10 CFR 35.2; and the provisions in 10 CFR 35.13 and 35.14; 35.26; 35.24(c); 35.24(d). If your request meets the requirements and/or criteria in these sections, it may be acceptable for you or your Radiation Safety Committee to internally evaluate and approve certain changes to your license and then use the notification processes described in these regulations, as appropriate.

For example, if a medical licensee wants to name an Authorized User (AU) physician to its license who is currently named to another NRC license for the exact same use, the licensee can allow that AU to begin work and utilize the notification process, as permitted by 10 CFR 35.13(b) and (c) and 35.14(a).]

We have noted that many licensees often add the word "expedite" or similar wording to their incoming correspondence, some almost routinely, thus creating an expectation that we will automatically interrupt work on cases already in queue to begin work on the cases requesting non-specific, unjustified and unsupported "expedites."

This is disruptive to our process and often such cases contain little or no other information to justify and support the "expedite" request, nor a date when it is needed by. In addition, these cases are often of poor quality and require more time to review than should be expected.

Therefore, to assist us in serving you better, and in order to serve all of our applicants and licensees fairly, please contact us by telephone ((630) 829-9887, or a specific reviewer, (if known) if an emergent medical situation or compelling business situation arises after you have submitted an amendment request to your license and if you can justify and support the need for that particular amendment/new license to be moved up in our normal reviewing queue.

Having this information enables our management to best decide how to handle your expedite request.

Please note that we normally process all licensing actions, including amendment requests, new license applications and renewals, in the order in which they are received, i.e., "first come, first served." We have conducted business in this manner for more than 26 years, as of 2019.

As stated in our acknowledgment card, sent to all who submit licensing applications for our review, the initial review for amendments and new license applications is normally completed within 90 days of receipt, as an internal goal only.

The initial review for renewals is normally completed within 180 days of receipt, again as an internal goal only.

The technical quality of your submission is a primary factor that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process.

Preparing your amendment requests carefully and in accordance with NRC's regulatory requirements and guidance, especially the documents in the NUREG 1556 series, as well as other information on our website at http://www.nrc.gov, will help ensure that your correspondence is complete and accurate in all material respects, as 10 CFR 30.9 (a) requires it to be.

If you know of a truly emergent medical situation that is unforeseen and beyond the circumstances of your control or a compelling business situation impacting your license and you need a licensing action completed by a certain specific date (not "stat" or "as soon as possible," etc.), please advise us of the particulars of the situation, the specific date when the new license or amendment is needed and the specific justification and support for it, which should be briefly summarized.

Calling us directly is quickest, (630) 829-9500; depending on the situation, email may be useful.

Faxing your application/ request to us at 630-515-1078 is usually the most quick and reliable method of transmission.

Only send one, complete, signed and currently dated application/ request.

Do not submit more than one copy or other copies by different means of transmission, as doing so introduces errors in processing, delays and confusion.

In addition, please briefly explain why your new license or amendment was not completed and submitted to us at least 90 days prior to the date when you needed it by.

As the volume of non-specific "expedite" requests we receive is quite large, this information is important to determine whether a reasonable effort was, could or should have been made on your part to prepare and submit the request in a sufficiently timely manner to permit our review without passing over the licensing requests of others who made their submissions earlier.

NRC expects the first vetting of all incoming licensing requests to be performed by the requesting licensee/applicant to ensure that the application is complete and accurate in all material respects, which will enable us to more readily assess whether to "expedite" it and act upon it more quickly, with less interference and impact to the cases in queue ahead of it.

Please also ensure that an appropriate senior management official (required by 10 CFR 35.12(a)) and/or your Radiation Safety Officer signs and dates the new license application or amendment request letter.

For expedite requests, it is preferable that a senior management official sign the request, as possible/appropriate.

Please include the name of at least one knowledgeable contact person who is familiar with your new license application or amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. A business email address for the contact person may also be helpful in many circumstances.

Please address all initial licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown below, unless you are directed to a specific, named reviewer for the immediate situation only.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system "Agencywide Documents Access and Management System" (ADAMS).

The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

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.

The NRC's Safety Culture Policy Statement became effective in June 2011.

While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at:

http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 13-18879-01
Docket No. 030-17305

Enclosure:

Amendment No. 61

Cc without enclosure:

Ms. Katie Shively
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Beacon Health System
Elkhart General Hospital
600 East Blvd.
P. O. Box 1329
Elkhart, IN 46515-1111