



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

DEC 27 2017

Steve Min, D.O.
Radiation Safety Officer
Genesys Regional Medical Center
One Genesys Parkway
Grand Blanc, MI 48439

Dear Dr. Min:

Enclosed is Amendment No. 17 to your NRC Material License No. 21-26740-01 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 please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078.

We prepared this amendment with our new Web Based Licensing system (WBL). As a result, we deleted Condition No. 13, as it appeared on Amendment No. 16, and we added reference to 10 CFR Part 71 in the Preamble at the top of page 1 of the license.

We also added ADAMS accession numbers to the documents listed in new Condition No. 13 and we re-ordered and more correctly identified these documents.

- A. We were unable to approve the requests to add authorization for iodine-125 seeds use, as permitted by 10 CFR 35.1000, and for Paul Kocheril, M.D. as an authorized user for the seeds used in this modality, because the information in the letter dated October 4, 2017, was insufficient to complete our review.

If you wish to pursue these authorizations, please provide only one response to items A.1. through 4. below. The following tips may assist you.

Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) correspondence document, such as either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a. Please ensure that the requested information is answered completely and accurately.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us. Please do not email a PDF document to us, and transmit a faxed version, and/or a hard copy sent by mail.

Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors.

Please address your written response to my attention as "additional information to control number 601361" to facilitate proper handling in our offices.

1. Please explicitly state that you want authorization for the iodine-125 seeds permitted by 10 CFR 35.1000 for the use of the localization of non-palpable lesions and lymph nodes.
 2. Please also respond in writing to all of the information in the online guidance on our website at: <https://www.nrc.gov/docs/ML1619/ML16197A568.pdf> that pertains only to this specific modality.
 3. Please specify how much total activity you wish to be authorized to possess for this modality.
 4. Please submit a revised "Delegation of Authority" (DoA) for your Radiation Safety Officer (RSO) that demonstrates he is qualified to serve as RSO for this new modality. Please see 10 CFR 35.50(d) and 35.50(e); and NUREG 1556 Vol. 9, Rev. 2, the last page in Appendix I, which is a sample DoA that may help you. The Forms NRC 313a (RSO) in Appendix B and the guidance for completing these forms in Appendix D, also in the afore-mentioned NUREG 1556, Vol. 9, Rev. 2, may be helpful.
- B. 10 CFR 35.24(b) states that "a licensee's management shall appoint a Radiation Safety Officer..." This is singular by intention.

However, your license shows a second Radiation Safety Officer (RSO), namely Ibrahim S. Abdulhay, Ph.D., for the manual brachytherapy program. This is not acceptable.

Please submit an amendment request within 30 days of the date of this letter (by the end of January 2018) removing Dr. Abdulhay as the RSO for the manual brachytherapy program, as "additional information to control number 601361" and addressed to my attention at the above address. Your written request must be currently dated and signed by a senior management representative. If an alternative timeframe to respond is needed, please contact me directly, as shown above.

Please submit an updated "Delegation of Authority" for your RSO, Steve Min, D.O., that includes the manual brachytherapy program. This must be currently signed by senior management and Dr. Min and be currently dated. Dr. Min will also have to demonstrate compliance with 10 CFR 35.50(d) and 35.50(e) for the manual brachytherapy program. Appendix I in the "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses (NUREG-1556, Volume 9, Revision 2)," at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/> contains a sample "Delegation of Authority."

Please also ensure that Dr. Ibrahim is made aware of this information and these changes.

- C. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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
Materials Licensing Branch

License No. 21-26740-01
Docket No. 030-34188

Enclosure:

Amendment No. 17