



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

FEB 06 2020

Steve Min, D.O.
Radiation Safety Officer
Ascension St. Mary's Hospital
800 S. Washington Ave.
Saginaw, MI 48601-2594

Dear Dr. Min:

Enclosed is Amendment No. 78 to your NRC Material License No. 21-03646-03 in accordance with your request. We have removed Drs. Khurshid Ahmad and Tushar Shah as authorized users on this license.

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.

1. Please note that, in this amendment, we were unable to approve Charbel A. Habib, Ph.D., as an Authorized Medical Physicist (AMP) for your high dose rate (HDR) remote afterloading brachytherapy program and as an authorized user for the cesium-137 survey instrument calibrator materials listed in Subitem Nos. 6. through 9.G. on the license. This is because the information in the letter dated November 14, 2019, signed by Stephanie Duggan, M.D., President and CEO for this hospital, was insufficient for us to complete our review.

Please be reminded that 10 CFR 30.33(a)(3) requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property.

This caution applies to both Dr. Habib and to Mr. Bachleda in Item 2 below.

Please provide a written response, following the instructions in Item 5 below.

- a. Please provide a copy of the actual board certification document for Dr. Habib, instead of the letter advising him that he passed the specialty certification board's oral exam and is considered certified.
 - b. Please provide the information required by 10 CFR 35.51(c).
 - c. Please provide specific details describing Dr. Habib's previous training and experience using the survey instrument calibrator.
2. We were unable to approve Paul Bachleda, M.S. as an authorized user for the cesium-137 survey instrument calibrator materials listed in Subitem Nos. 6. through 9.G. on the

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

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license. This is because the information in your letter dated November 14, 2019, was insufficient for us to complete our review.

Please provide a written response, following the instructions in Item 5 below.

- a. Please provide specific details describing Mr. Bachleda's previous training and experience using the survey instrument calibrator.
3. In the course of our review of your license, we noted that this license does not contain procedures or descriptive information for the use of the survey instrument calibrator device.

I checked your renewal application dated August 28, 2014, and all the documents listed in Condition No. 16 of your license that support your licensed program. I did not find this information included so it appears to be an oversight that we must now correct.

The absence of this information renders your license incomplete and, whether you pursue the authorizations for Dr. Habib and/or Mr. Bachleda above, you must complete your license now by providing this information.

Please use NUREG 1556 Vol. 9, Rev. 3, Appendix K, to prepare an appropriate written response, which may be found on our website at: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/>.

Please provide this response within 30 days of the date of this letter (by March 11, 2020). If an alternate timeframe is needed to respond, please contact me at colleen.casey@nrc.gov (best). Please follow the instructions in Item 5 below.

If you have any questions concerning this request, or any of the other items in this letter, please contact me via email to set up a mutually convenient date and time for a telephone discussion.

4. In the course of this review, we noticed that Subitem No. 9.H. authorizes you for two different high dose rate remote (HDR) afterloading brachytherapy devices when it appears that you are only using one such device at one location of use.

This is also a matter that we must address at this time, in order to keep your license current and accurate. Please provide this response also within 30 days of the date of this letter (by March 11, 2020).

- a. Please explain why you are authorized for two different HDR devices and if one of the devices authorized should no longer be listed on the license, please explain and direct us to remove the specific device.
- b. Please state when the device was removed from your location of use and by whom, i.e., which licensed entity took possession of it. Please follow the instructions in Item 5 below for your response.

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5. In order to submit your written responses to the above items, where we have asked for them (and/or if you choose to pursue them, for Items 1 and 2), please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) response correspondence document, including either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a that permits us to identify your license.

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. If you resubmit such information only for the sake of adding context and other details to enhance its meaning, that is acceptable.

Please do not email a PDF document to me, 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, although emailing a PDF document is the least efficient mechanism for responding to me.

The most reliable and fastest way to respond is to send a fax of one complete copy only to me at (630) 515-1078. Please do not email your written response to me.

Please address your written response to my attention as "additional information to control number 617017" to facilitate proper handling in our offices.

We also noted that your letter dated November 14, 2019, did not list a point of contact, a telephone number, email address, etc. if we should have questions concerning your requests.

Please always provide the name, direct telephone number, fax number and email address for at least one point of contact in every licensing request that you make.

Please also be reminded that 10 CFR 30.9(a) requires: "(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."

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

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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 (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
Materials Licensing Branch

License No. 21-03646-03
Docket No. 030-02031

Enclosure:

Amendment No. 78