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

MAY 23 2018

Donald J. Conn, M.D.
Radiation Safety Officer
Beaumont Hospital - Dearborn
18101 Oakwood Boulevard
Dearborn, MI 48124

Dear Dr. Conn:

Enclosed is Amendment No. 124 to your NRC Material License No. 21-04515-01 in accordance with your request.

If you have any other 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.

At this time we were unable to approve Daniel Hamstra, M.D. as an authorized user for materials in 10 CFR 35.400 and 35.600, limited to iridium-192 in a high dose rate (HDR) remote afterloading brachytherapy device.

This is because the information in your letter dated March 12, 2018, was insufficient to complete our review. Please provide the additional information requested below addressed to my attention as "additional information to control number 602663." We will then continue our review.

The supporting documents for Dr. Hamstra's application failed to include information demonstrating that he meets the requirements in 10 CFR 35.59, "Recentness of Training." His specialty board certification was obtained more than 7 years prior to the date of his application to become an authorized user so 10 CFR 35.59 must be complied with. In fact, his certificate states that it is valid through 2017, yet it was submitted to us as an attachment to your letter dated March 12, 2018. 10 CFR 35.59 is on our website at https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0059.html.

In addition, from the documents provided, it appeared that the most recent training and experience he had using the HDR device was also more than 7 years ago, in January 2009 for device operations and safety procedures and in June 2005 for clinical use.

We are also unable to verify Dr. Hamstra's preceptor physician, Edgar Ben-Josef, M.D., who references himself as an authorized user on the Type A medical broad scope license for the University of Michigan. Type A medical broad scope licenses do not name authorized users, etc. on the license directly. Instead, they have Radiation Safety Committees (RSC) who evaluate and approve or disapprove of authorized users, etc. internally.

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

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Please provide information demonstrating that Dr. Hamstra meets the requirements in 10 CFR 35.59 and please submit a copy of a letter from the Chairperson of the RSC for the University of Michigan that stipulates Edgar Ben-Josef, M.D. was or is an authorized user for the modalities that he preceptored Dr. Hamstra for during the timeframes when Dr. Hamstra trained under Dr. Ben-Josef.

The following references may be of assistance to you in preparing your response and for future amendment requests and you are strongly encourage to consult these resources to help ensure that your correspondence with us is complete in all material respects, as required by 10 CFR 30.9 (at https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/part030-0009.html):

NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Medical Use" contains sections that are informative and instructive, including, but not limited to, Appendix D, Sections III, IV, V, and XI. It can be found on our website at: https://www.nrc.gov/docs/ML0734/ML073400289.pdf

Our Materials Licensing toolkit website contains a wealth of information to assist you and it can be found on our website at: https://www.nrc.gov/materials/miau/med-use-toolkit/reg-issues-sum.html

This toolkit contains sections that include Regulatory Issue Summaries (RISs) and Information Notices (INs) that are of interest to medical users. Certain specific RISs and INs pertaining to recentness of training for authorized users and completeness and accuracy of information provided to the commission in documentation of training and experience for proposed authorized users, among other topics, can be found at the following links on our website at:

https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf

https://www.nrc.gov/materials/miau/med-use-toolkit/info-notices.html

https://www.nrc.gov/docs/ML0722/ML072270127.pdf

https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2002/in200236.pdf

https://www.nrc.gov/materials/miau/med-use-toolkit.html#other

https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

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 (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. 21-04515-01
Docket No. 030-02051

Enclosure:
Amendment No. 124