



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

NOV 22 2017

Tyre K. Jones, IV, M.D.
Radiation Safety Officer
McLaren Medical Center Bay Region
Nuclear Medicine
1900 Columbus Avenue
Bay City, MI 48708

Dear Dr. Jones:

Enclosed is Amendment No. 63 to your NRC Material License No. 21-18585-01 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 or concerns about our disposition of these matters, please contact me directly at (630) 829-9841. My fax number is (630) 515-1058.

Please note that we were unable to approve your request to add Jose L. Pino-y-Torres, M.D., as an authorized user (AU) to your license for the use of materials in 10 CFR 35.400 (limited to iodine-125) and 35.600 (limited to iridium-192 in a high dose rate remote afterloading brachytherapy device). This is because the information in your letter dated August 23, 2017, was insufficient to complete our review.

If you wish to pursue this matter, please submit a written, currently dated and signed (by a senior manager) business-style letter that contains the identifying information in NRC Form 313, or an NRC Form 313, and reference it to my attention as "additional information to control no. 600653."

On the referenced license you provided with your August 23, 2017, letter, we noted that the name "Jose L. Pino-y-Torres, M.D." does not appear in the list of AUs. The name "Jose L. Pino, M.D." appears on the referenced license. If this is the same person as "Jose L. Pino-y-Torres, M.D.," please explain the discrepancy in the name, i.e., has this name been legally changed? If so, when, and please provide documentation for the legal name change.

In addition, we noted that the referenced license expired July 31, 2003, more than 14 years prior to the date of application. Yet no evidence of recentness of training was provided in your letter dated August 23, 2017, as required by 10 CFR 35.59.

Please provide written evidence of recentness of training, in accordance with 10 CFR 35.59, and as instructed above for response.

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

Please refrain from submitting resumes or curricula vitae to support this request, as it will likely contain much information that we do not need and little, if any, information that we do need.

The following Regulatory Issue Summary 2003-17 and Information Notice 2007-38, available on our website at the following links, may assist you:

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

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

In addition, you may refer to the regulations in 10 CFR 35.57 and 35.59 at: <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/> and to NUREG 1556 Vol. 9, Rev. 2, at: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>, especially the appropriate sections about AUs and Appendices B and D.

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
Materials Licensing Branch

License No. 21-18585-01
Docket No. 030-13900

Enclosure:

Amendment No. 63