



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
FEB 14 2007

Bashir Pothiawala, M.S.
Radiation Safety Officer
Methodist Hospital of Gary, Inc.
8701 Broadway
Merrillville, IN 46410

Dear Mr. Pothiawala:

Enclosed is Amendment No. 54 to your NRC Material License No. 13-16558-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

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.

Please refer to RIS 2005-31 at

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf>

A hard copy of this document should have been sent to you already. Please refer to Table 1, Attachment 2, page 19 of 19, especially and note the activity thresholds listed for materials commonly included in 10 CFR 35.400.

At this time please specify which radionuclides in 10 CFR 35.400 you want authorization for and please include manufacturer's names/model numbers and **especially possession limits** for each radionuclide. Please also specify a total possession limit for iodine-125 lotrex in Subitem No. 8.I.

We must now review license applications and prepare license documents in accordance with this RIS and the requested information is necessary to complete that review.

At this time I added a new Condition No. 16, which effectively limits your possession of iodine-131 in 10 CFR 35.300 to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

In your next amendment please specify a possession limit for iodine-131 in 10 CFR 35.300 that will enable us to then remove this Condition. Your possession limit must be less than ten curies, be realistic for your needs and include waste stream activities as well. Many licensees typically request one curie for this purpose.

Please note that I was unable to approve Paul D. Crossan, M.D. as an authorized user for materials in 10 CFR 35.300, iridium-192 in an HDR remote afterloading brachytherapy device,

cobalt-60 in the Gamma Stereotactic Radiosurgery Device and iodine-125 in the Proxima Therapeutics Gliasite Radiotherapy system because the information submitted in your letter dated December 7, 2006, was insufficient to complete my review.

If you wish to pursue this matter, please submit the following information, addressed to my attention and referenced as "additional information to control number 315915."

I only authorized Dr. Crossan for the use of materials in 10 CFR 35.400 because that was the only authorization he had on the referenced Agreement State license you submitted.

Please note that we cannot accept Dr. Crossan's specialty board certification, as of October 25, 2005.

Dr. Crossan was not approved as an authorized user for the use of materials in 10 CFR 35.300, iridium-192 in an HDR remote afterloading brachytherapy device, cobalt-60 in the Gamma Stereotactic Radiosurgery Device and iodine-125 in the Proxima therapeutics Gliasite Radiotherapy system because his training and experience did not appear to meet the requirements in 10 CFR 35.390, 35.690, 35.1000 (as it pertains to the guidance on our website for iodine-125 in the Cytoc Surgical Products Gliasite Radiotherapy system) and 35.59.

Please refer to the regulatory requirements in 10 CFR 35.390, 35.690, 35.1000 (as it pertains to the guidance on our website:

"<http://www.nrc.gov/materials/miau/med-use-toolkit/liquid-brach.html>" for iodine-125 in the Cytoc Surgical Products Gliasite Radiotherapy system) and 35.59, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 1, for assistance in preparing your response.

If Forms 313a will be used in support of your response, please use the newly revised Forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

In addition, since Dr. Crossan is certified by a medical specialty board that we no longer accept, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

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

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025. My fax number is 630-515-1078.

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.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 13-16558-01
Docket No. 030-11234

Enclosure:

Amendment No. 54