



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

JUL 25 2005

William N. Salk, M.S.
Radiation Safety Officer
St. Cloud Hospital Imaging Services
1406 Sixth Avenue North
St. Cloud, MN 56303

Dear Mr. Salk:

Enclosed is Amendment No. 52 to your NRC Material License No. 22-10258-01 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.

- A. Please note that we were not able to approve your requests to delete authorization of iridium-192 in the Cordis Checkmate System and strontium-90 in the Novoste Model A1000 series intravascular brachytherapy system from your license and to add iodine-125 Iotrex in the Gliasite RTS system to your license at this time because the information provided in your letter dated April 29, 2005, was insufficient to complete our review.

If you wish to pursue these requests please submit the information below, addressed to me and reference control number 314448. We will then continue our review.

1. Please submit a copy of acknowledgments of receipt from the appropriate vendors who took possession of your final sources and devices for iridium-192 in the Cordis Checkmate System and strontium-90 in the Novoste Model A1000 series intravascular brachytherapy system. The acknowledgments of receipt must show that the vendors received your last active sources and devices and were appropriately licensed to take possession of these sources/device.

10 CFR 30.41 and 30.51 require this information and we must review it before we can amend your license to remove the iridium-192 in the Cordis Checkmate System and strontium-90 in the Novoste Model A1000 series intravascular brachytherapy system authority from your license. Your vendors should have sent this information to you automatically when you returned the last sources/device.

2. Please also provide copies of the most recent leak tests for each of the last sealed sources you possessed for the iridium-192 in the Cordis Checkmate System and strontium-90 in the Novoste Model A1000 series intravascular brachytherapy system intravascular brachytherapy system.
3. In order to save time and effort, it is always best to prepare licensing correspondence in accordance with NUREG 1556, Vol. 9, Rev. 1, Final, especially Appendix C and Tables C.1, C.2 and C.3. In addition, guidance specific to the Gliasite product and 10 CFR 35.1000 can be found on our website at

<http://www.nrc.gov/materials/miau-reg-initiatives/liquid-brach.html>

Commitments we will require to complete this action can be found in the attached excerpt from this webpage. Please commit to, specifically confirm and/or describe those items noted in the attachment.

Please confirm that all other radiation safety program elements, currently authorized by your license for the use of materials in 10 CFR 35.400, will be followed for the use of the iodine-125 Iotrex in the GliaSite RTS system, **except** as specifically noted otherwise.

Please note that, although the SDDR certificate for the I-125 GliaSite does not require a leak test, NRC does require leak test - type evaluations of the GliaSite product.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025.

- B. 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically 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 enclosed license document is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 22-10258-01
Docket No. 030-02241

Enclosure:

1. Amendment No. 52
2. GliaSite Guidance,
NRC webpage excerpt