



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

JAN 16 2018

James M. Forde, M.D.
Radiation Safety Officer
Porter Regional Hospital
85 East U.S. Highway 6
Valparaiso, IN 46383

Dear Dr. Forde:

Enclosed is Amendment No. 50 to your NRC Material License No. 13-17073-01 in accordance with your request dated September 22, 2017.

In this amendment, we approved the authorization of Omar Barakat, M.D. for the use of yttrium-90 as SIR-Spheres, as permitted by 10 CFR 35.1000. Your letter dated September 22, 2017, making this requested authorization for Dr. Barakat, was reviewed originally under control number 601055.

We sent a letter requesting additional information to you and to your consultant, Thomas Kumpuris, on September 27, 2017, to which we received no response. Mr. Kumpuris agreed that we should void that request until a response was prepared. We subsequently voided this request.

However, in reviewing the correspondence involved in the proposed HDR program, we noted that Amendment No. 49 had been issued to you by another reviewer and that this amendment resolved the concern we had in writing our letter to you dated September 27, 2017, for additional information.

Therefore, we have concluded that Dr. Barakat is qualified for the use of yttrium-90 as SIR-Spheres, as permitted by 10 CFR 35.1000. This amendment reflects his new authorization.

We apologize for the error in reviewing the original request for Dr. Barakat's additional authorization and for any inconvenience it may have caused.

We found that we needed additional information from you in order to complete our review of the proposed HDR program. This request for additional information (RFAI) was transmitted to you in a separate letter dated January 16, 2018. The RFAI letter was also faxed to your designated point of contact for the proposed HDR program, Gary Dillon, M.S., also on January 16, 2018. Instructions for response are contained in the RFAI letter.

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 concerning this amendment, or the additional information requested below, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841.

My fax number is (630) 515-1078 and my email address is colleen.casey@nrc.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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. 13-17073-01
Docket No. 030-12150

Enclosure:

Amendment No. 50