



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

OCT 16 2017

Randall J. Phillips, M.D.
Radiation Safety Officer
QHG of Indiana, Inc.
7950 West Jefferson Boulevard
Fort Wayne, IN 46804-1677

Dear Dr. Phillips:

Enclosed is Amendment No. 77 to your NRC Material License No. 13-01535-01 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 concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078.

Please note that we were unable to approve your request to name Saad Ibrahim, M.D. for the use of yttrium-90 SirSpheres, permitted by 10 CFR 35.1000, at this time because the information provided in your letter dated February 17, 2017, received July 20, 2017, was insufficient to complete our review.

If you wish to pursue this request, please prepare a written response that is currently dated and signed appropriately and transmit the information requested with an accompanying business-style letter addressed to my attention at the address above as "additional information to Control No. 600227."

Please only submit one complete request by only one means of transmission and please note that sending it via either regular mail or fax to 630-515-1078 is best.

Dr. Ibrahim was not approved for the use of yttrium-90 SirSpheres, permitted by 10 CFR 35.1000 because his specialty board certification does not say anything about interventional radiology and he does not meet the training and experience criteria in 10 CFR 35.390(b)(1)(ii)(G)(3), as required in the licensing guidance on our website for yttrium-90 SIRSpheres, dated February 2016, in section A.1. These reasons also preclude his qualifying under Sections A.2. and A.3. in that same licensing guidance.

These deficient issues must be addressed before we can continue our review.

In addition, we noted that your letter dated February 17, 2017, received July 20, 2017, was on "Lutheran Health Network, Lutheran Hospital" letterhead, although the name for this license is "QHG of Indiana, Inc." There is no "doing business as" name affiliated with your license. Please either explain why this letterhead is being used for QHG of Indiana,

Inc. or, preferably, use an NRC Form 313 form to capture the identifying and other information needed to make an amendment request to us. You may then add extra pages as needed to describe, justify and support your request without using letterhead that does not identify your license. This method will help to mitigate errors introduced into the licensing process in the future.

The NRC Form 313 can be found at:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf>

If the NRC Form 313 is not used, then a business letter containing all of the information on the NRC Form 313 may be used instead, preferably letterhead with the name of the licensee.

In addition, your letter dated February 17, 2017, received July 20, 2017, directs us to "contact us" if we have any questions. This letter is signed by Scott Weiskittel, C.O.O. No other contact person's name, phone number, fax number and email address are provided for us to contact you.

In preparing all future licensing correspondence, please advise us of the name of at least one knowledgeable person whom we may contact for questions, including his or her direct line telephone number, fax number and email address.

In preparing your response, please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

What this means, in part, is that the first vetting of any licensing request is expected to be made by the requesting applicant/licensee, against the regulations, license requirements and guidance involved. Only after the request has been thoroughly vetted by the applicant/licensee should the licensing correspondence be transmitted to NRC.

This is the expectation that NRC uses to most efficiently process and review in a timely manner the many licensing actions received. The quality of the incoming request is a primary determining factor that only the applicant/licensee can control that enables NRC to serve and protect the public and the environment.

You will note that your license has been prepared using our new Web Based Licensing system. In conjunction with this, we deleted Condition No. 13, as it appeared on Amendment No. 76, in favor of referencing 10 CFR Part 71 in the Preamble at the top of page one of your license.

We also added ADAMS accession numbers for all documents listed in your final, "tie-down" condition.

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,

A handwritten signature in black ink that reads "Colleen Carol Casey". The signature is written in a cursive, flowing style.

Colleen Carol Casey
Materials Licensing Branch

License No. 13-01535-01
Docket No. 030-01594

Enclosure:

Amendment No. 47