



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

AUG 01 2016

Laura T. Smith, M.S., DABR  
Radiation Safety Officer  
St. John Macomb-Oakland Hospital – Macomb Center  
11800 E. 12 Mile Road  
Warren, MI 48093

Dear Ms. Smith:

In letter dated April 1, 2016 (ML16153A217), you requested that James Min Kim, M.D. be added to your license, NRC License No. 21-01190-05, for the medical use of radioactive material for diagnostic purposes – as permitted by Title 10 of the *Code of Federal Regulations* Sections 35.100 and 35.200. You provided an NRC Form 313A(AUD) and an American Board of Radiology (ABR) certificate. As noted in our previous correspondence, the submitted ABR certificate did not meet 10 CFR 35.290(a) stipulations in that there was no "AU Eligible" designation. Further, also as noted in previous correspondence and during our phone conversation on July 27, 2016, the NRC Form 313A(AUD) provided did not meet the training and experience requirements of 10 CFR 35.290(c). We have noted that you had previously made the same request under letter dated August 1, 2015 (ML15236A293). The NRC license reviewer for that action requested additional training and experience information but any information provided in that request did not meet 10 CFR 35.290 requirements. Once again and as discussed, submitted training and experience for Dr. Kim does not meet NRC requirements. Also as discussed, we have observed unaccounted for discrepancies between your previous and current requests to add Dr. Kim as an AU.

Accordingly, Dr. Kim cannot be added to your license at this time and as such this request is voided without prejudice. If you wish to pursue adding Dr. Kim to your license in the future, please review the aforementioned training and experience requirements and provide a current and complete NRC Form 313A(AUD) showing 700 hours of training and experience (a minimum of 80 hours of classroom and laboratory training) including eluting generator systems (see 10 CFR 35.290(c)(1)(ii)(G)).

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.

L. Smith

- 2 -

As discussed via phone and as noted in previous correspondence, please be reminded that **10 CFR 30.9 and 30.10 require that information** provided to the Commission by a licensee to **be complete and accurate** in all material aspects. Deliberate **submittal of incomplete or inaccurate information** that is material to the Commission **could subject the licensee to enforcement action.**

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.

In accordance with 10 CFR 2.390, a copy of this letter 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>. If you have any questions, please contact me at (630) 829-9887.

Sincerely,



Sara A. Forster, M.S.  
Health Physicist  
Materials Licensing Branch

License No. 21-01190-05  
Docket No. 030-02005