



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

JUL 07 2016

Annie Kalapparambath, M.D.
Radiation Safety Officer
Crittenton Hospital Medical Center
1101 W. University Drive
Rochester, MI 48307

Dear Dr. Kalapparambath:

Enclosed is Amendment No. 74 to your NRC Material License No. 21-13562-01 in accordance with your request, with the exception of adding Neal Hall, M.D. as an Authorized User (AU). As discussed with your physicist, Michelle L. Kritzman, documentation submitted to demonstrate Dr. Hall's completion of required training and experience was insufficient to meet NRC requirements. In addition, please note that we have deleted Condition No. 13 in accordance with current NRC policy to include the reference to Title 10 of the *Code of Federal Regulations*, Part 71, "Packaging and Transportation of Radioactive Material," in the preamble, on page 1 of the license.

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.

As discussed with Ms. Kritzman (your designated licensee contact) on June 2, June 20, and July 5, 2016, support for the request to list Dr. Hall AU on the above-referenced license was limited to a copy of Dr. Hall's American Board of Radiology (ABR) certification, marked with an effective date of October 2, 2015. Dr. Hall's preceptor forms (submitted forms NRC 313A (AUD) and 313A (AUT) both signed by you on May 20, 2016) excluded detailed descriptions of either Dr. Hall's classroom and laboratory training or supervised work and clinical experience, as specified in 10 CFR Sections 35.290(c), 35.392(c), and 35.394(c).

We have noted that Dr. Hall's ABR certificate does not include the words "AU Eligible" above the seal, as required by 10 CFR 35.290(a), 10 CFR 35.392(a), and 10 CFR 35.394(a), where the listing of "Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35" may be found at the NRC's website:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

Although the request to add Dr. Hall included an unsigned January 14, 2016 letter from Valerie P. Jackson, M.D., Executive Director for the ABR, that letter cannot be accepted as a substitute for the recognized board certificates listed at the NRC website, as it fails to meet the requirements in 10 CFR 35.290(a), 10 CFR 35.392(a), and 10 CFR 35.394(a).

To resubmit your request to add Dr. Hall as an AU, please request the same via a signed and dated letter, indicating whether the request is via the (1) Board Certification or (2) Alternate Training and Experience (T&E) pathway.

(1) If using the Board Certification pathway under 10 CFR 35.290(a), 35.392(a), and 35.394(a), please include the following information:

- A copy of an updated ABR certificate for Dr. Hall bearing the words "AU Eligible" above the seal (as listed at the NRC website);
- Preceptor attestation for Dr. Hall's 10 CFR 35.200 competencies (copies of pages 1 and 4 of the May 20, 2016, NRC Form 313A (AUD) signed by you would be acceptable); and
- Preceptor attestation for Dr. Hall's 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131) competencies (copies of pages 1, 4, 5, and 6 of the May 20, 2016, NRC Form 313A (AUD) signed by you would be acceptable).

(2) For the Alternate T&E pathway under 10 CFR 35.290(c), 35.392(c), and 35.394(c), please include sufficient detail to demonstrate that topical and time requirements have been met. This may be completed by submitting updated signed copies of:

- Pages 1 through 4 of an NRC Form 313A (AUD), documenting classroom and laboratory training, supervised work experience hours, and including a preceptor attestation by a qualified AU; and
- Pages 1 through 6 of an NRC Form 313A (AUT), documenting classroom and laboratory training, supervised work experience hours, and supervised clinical experience, and including a preceptor attestation by a qualified AU.

For quickest processing, please resubmit any request to add Dr. Hall as an AU via facsimile, to the attention of the Materials Licensing Branch, at (630) 515-1078.

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 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>.

Sincerely,



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

License No. 21-13562-01
Docket No. 030-02157

Enclosure: Amendment No. 74