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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

JAN 18 2017

Thomas J. Moenster
Radiation Safety Officer
Missouri Baptist Medical Center
3015 N. Ballas Rd.
St. Louis, MO 63131

Dear Mr. Moenster:

Enclosed is Amendment No. 87 to your NRC Material License No. 24-11128-02 in accordance with your request dated November 9, 2016 (ML16320A217), with the exception of adding Gerald Palagallo, M.D., as an Authorized User (AU). Please also note that we have deleted Condition No. 14 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.

Please review the enclosed license amendment 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) 829-9892 so that we may provide appropriate corrections and answers.

We have reviewed your request to add Dr. Palagallo as an AU for byproduct material as permitted under 10 CFR 35.100, 35.200, and 35.300. Although the request contained a record of supervised oral iodine I-131 cases, as required under 10 CFR 35.392(c)(2)(vi) and 10 CFR 35.394(c)(2)(vi), it contained no documentation of additional training, experience, or preceptor attestations, as required under 10 CFR 35.290, 35.392, and 35.394. In addition, we were unable to verify that the "preceptor" for Dr. Palagallo's supervised oral iodine I-131 cases is an AU authorized for 10 CFR 35.100, 35.200, and 35.300 uses, because the referenced University of Washington radioactive materials license is a broad scope license. Accordingly, AUs are not listed on that license.

To add Dr. Palagallo as an AU, please resubmit your request, including training and experience documentation and preceptor attestations sufficient to meet requirements outlined in 10 CFR 35.290, 35.392, and 35.394. You may use the NRC Forms 313A (AUD) and 313A (AUT) to provide the necessary documentation. Those forms may be found at

https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf and
https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aut).pdf.

Documentation needed for authorizations required under 10 CFR 35.200 (per 10 CFR 35.290), 35.392, and 35.394:

(1) Location, dates, and total hours for classroom and laboratory training including topics:

a. Radiation physics and instrumentation;

The enclosure to this letter contains sensitive security-related information. When separated from this cover letter this letter is uncontrolled.

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of byproduct material for medical use; and

e. Radiation biology;

(2) Location, License No., dates, name of supervising AU*, and total hours for supervised work experience in topics required for 10 CFR 35.100 and 35.200 authorizations:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

f. Administering dosages of radioactive drugs to patients or human research subjects; and

g. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs;

(3) Location, License No., dates, name of supervising AU*, and total hours for supervised work experience in topics required for 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131) authorization:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of byproduct material;

e. Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

f. Administering sodium iodide I-131 dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of 1.22 gigabecquerels (33 millicuries) or less, and 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries);

(4) Sodium iodide "I-131 Therapy Experience Log" (resubmitted) or other documentation of at least three cases for each 10 CFR 35.300 authorization sought;

(5) Preceptor attestation as specified in 10 CFR 35.290(c)(2); and

(6) Preceptor attestation as specified in 10 CFR 35.392(c)(3) and 35.394(c)(3).

* NOTE: If the supervising AU is authorized via a permit issued by a Radiation Safety Committee (RSC) under a broadscope license, please also include a letter or certificate from that licensee's Radiation Safety Officer (RSO), Alternate Radiation Safety Officer (ARSO), and/or RSC Chairperson. The letter should indicate the authorizations (10 CFR 35.100, 35.200, 35.300, etc.) of the supervising AU and the dates on which those authorizations were effective. Your resubmitted request should be under a signed and dated cover letter, addressed to our office, attention "Materials Licensing Branch." You may submit the request via regular mail or via facsimile to (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.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with Title 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

In accordance with Title 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 Publicly Available Records component of NRC's ADAMS, which is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Sara A. Forster

Sara A. Forster, M.S., Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 24-11128-02
Docket No. 030-08325

Enclosure: Amendment No. 87