

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

AUG 05 2013



Douglas M. Frye, Ph.D.
Radiation Safety Officer
Indiana University Health Arnett, Inc.
420 North 26th Street
Lafayette, IN 47904

Dear Dr. Frye:

Enclosed is Amendment No. 17 to your NRC Material License No. 13-32087-01 in accordance with your request. Please note that the major 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.

- A. **This also refers to your letter received June 14, 2013, which requests authorization for Matthew Orton, M.D. as an authorized user for materials in 10 CFR 35.600, limited to high dose rate remote afterloading brachytherapy (HDR).**

We were unable to approve Dr. Orton at this time because the information provided in your letter received June 14, 2013, was insufficient to complete our review.

If you wish to pursue this matter, please provide a complete, written response that is currently dated and signed by a senior management official for your license, addressed to my attention at the above address, as "additional information to control number 581095." We will then continue our review.

Please note that the control number above is different from the control number listed on your letter received June 14, 2013. The control number on your letter was "317354," which was assigned to a licensing action requested by you in November 2008. It has not been used since then.

Control numbers are assigned by us for each correspondence from an applicant or licensee that initiates a new licensing request or revisits licensing requests that were not resolved initially. Once all licensing requests from a particular

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

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correspondence/control number are resolved, that control number is no longer valid. So control number 317354 has not been valid since 2008, when the licensing requests made at that time were resolved.

Dr. Orton's request to become an authorized user for materials in 10 CFR 35.600, limited to high dose rate remote afterloading brachytherapy, must be supported by the description of his education, training and experience on his Forms NRC 313a (AUS), as attested to by a qualified authorized user/preceptor for the same modality. A key part of this supporting documentation consists of verification of his preceptor, Dr. Song.

His Forms 313a (AUS) were signed by one of his "Supervising individuals," Shiyu Song, M.D. on May 29, 2013, representing Virginia Commonwealth University, license number VA 760-215-1, which an Agreement State licensee.

NRC does not have direct jurisdiction over this licensee; the Commonwealth of Virginia does and it administers this license. NRC does not have access to this license, which is needed to assist in the verification of the preceptor, Dr. Song.

If this license is a broad scope medical license, then Dr. Song's name will not appear on the license itself. The Radiation Safety Committee for broad scope medical licenses evaluates and approves/disapproves of authorized users internally.

Please submit a complete, current, signed and un-redacted copy of the Virginia Commonwealth University license that shows it is authorized for HDR use and either Dr. Song's name on this license as an authorized user for HDR use or a signed, dated letter from the Chairperson of the licensee's Radiation Safety Committee attesting that Dr. Song was an authorized user from 2009 to May 29, 2013, when he supervised and preceptored Dr. Orton.

Please refer to the regulatory requirements in 10 CFR 35.690 and section 8.12, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your written response to demonstrate that Dr. Song is qualified to serve as preceptor. Section V. in Appendix D references the information we are requesting.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

Please do not resubmit any documents you have already submitted.

- B. Please also note that we deleted Condition No. 14, as it appeared on Amendment No. 16, because this condition was no longer necessary.

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. My email address is colleen.casey@nrc.gov.

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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 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>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

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>.

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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 cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 13-32087-01
Docket No. 030-34812

Enclosure:
Amendment No.17 |