



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 28, 2010

Docket No. 03038332
Control No. 573263

License No. 06-00183-07

Peter Salovey, Ph.D.
Provost
Yale University
Environmental Health and Safety
135 College Street, First Floor Suite 100
New Haven, CT 06510

SUBJECT: YALE UNIVERSITY, NEW LICENSE, CONTROL NO. 573263

Dear Dr. Salovey:

This refers to your request for an NRC license. Enclosed with this letter is the license. 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 I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

Please note that this license for medical use of research radiopharmaceuticals of PET material is being issued prior to our completing your request for amendment to your broad scope license (L.N. 06-00183-03), which was submitted for NRC review on October 27, 2010. Your current use of the materials in this area (e.g., radiochemistry/QC and radiopharmaceutical preparation for medical research use under this license) may continue as currently provided under 10 CFR 30.3 until the broad scope license is amended. Issuance of your license for production of accelerator byproduct materials was issued on October 27, 2010.

Additionally, please note that Drs. Sinusas and Russell have been authorized for licensed material in 10 CFR 35.100 and 35.200 based on their prior approvals for these uses on NRC L.N. 06-31070-01 and the Broad Scope Permit submitted by Yale New Haven Hospital. Finally, we understand that you will ensure the implementation of your radiation safety procedures (occupational monitoring, area surveys, etc.) in accordance with commitments made in your broad scope license application dated January 27, 2005 (not January 31, 2005, as indicated in your response). Please inform us immediately if our understanding is incorrect.

When submitting future license amendments, please have the document signed by a management representative rather than the Radiation Safety Officer. The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs in the statements and representations contained therein. In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). Please complete the enclosed NRC Form 531, "Request for Taxpayer Identification Number" and mail to the address at the bottom of the form (Note 5).

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., calibration of dose calibrators, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify the NRC in writing when:
 - a) an authorized user, authorized nuclear pharmacist, or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
 - b) the mailing address changes;
 - c) the name on the license changes; or
 - d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license
 - a) when you decide to terminate all activities involving materials authorized under the license; or
 - b) if you decide not to acquire or possess and use authorized material.
4. Request and obtain a license amendment before you:
 - a) permanently change Radiation Safety Officers;
 - b) receive byproduct material in excess of the amount, or radionuclide, or form

different than authorized on the license;

- c) add or change the areas of use, except as allowed by 10 CFR 35.13(e) and with the appropriate notification described in 10 CFR 35.14(b)(4);
 - d) change the name or ownership of your organization;
 - e) change the address(es) of use identified on the license;
 - f) receive, prepare, or use byproduct material for a type of use that is not authorized on the license; or
 - g) permit anyone to work as an authorized user or authorized nuclear pharmacist, except as allowed by 10 CFR 35.13(b) and with the appropriate notification described in 10 CFR 35.14(a).
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the 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, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:300 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera
Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

P. Salovey

4

Enclosures:

1. NRC Form 531
2. License No. 06-00183-07

cc:

Tammy Stemen, C.H.P., Radiation Safety Officer

DOCUMENT NAME: G:\WordDocs\Current\Lic Cvr Letter\L06-00183-07.573263.doc

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