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REGION 1

The John B. Pierce Laboratory

Affiliated with Yale University

December 13, 2004

David B. Everhart
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1 Office
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Center for Research in
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RE: License No. 06-02354-02

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Dear Mr. Everhart:

Please find the enclosed revised supplement to the application for NRC License renewal for The John B. Pierce Laboratory. This revised supplement is in response to your letter dated November 9, 2004. I have added the requested information to the supplement, indicated in *italics text*. Specifically,

- Item 1. See Item 6, page 1.
- Item 2. See Item 8, page 2.
- Item 3. See Item 9 (receipt), page 2-3, and Item 10, Part 3, page 3-4.
- Item 4. See Item 10, Part 7, page 4-5.

Please do not hesitate to contact me if any questions arise or any further information is needed.

Sincerely,

P. Darrell Neuffer, Ph.D.
RSO

135748

NMSS/RCNI MATERIALS-002

Item 5. RADIOACTIVE MATERIAL

Unsealed materials

H ³	Liquid	Bound	60 millicuries
C ¹⁴	Liquid	Bound	40 millicuries
P ³²	Liquid	Bound	10 millicuries
I ¹²⁵	Liquid	Bound	5 millicuries

Sealed materials

Alpha/Beta/Gamma calibration standards for counters <1 uCi total

Item 6. PURPOSE FOR WHICH RADIOACTIVE MATERIAL WILL BE USED

- All isotopes listed are and will be used only for research and development as defined in 10 CFR 30.4.
Note that use of Sodium-24, Sulfur-35, Calcium-45 and Rubidium-86, although included on the previous license, are not requested for the current license renewal. These materials have been used previously but are not now in use.
 - i. *All materials have been removed from the Pierce Laboratory, including waste material.*
 - ii. *Records of information, important to decommissioning, required by 10CFR 30.35(g) are maintained.*

Item 7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

RSO

- *Name of proposed RSO – P. Darrell Neufer, Ph.D.*
- *Training and experience of RSO - Dr. Neufer received his Ph.D. in Biochemistry in 1993 and has worked with radioactivity in his research since 1989. He has worked primarily with ³²P (as much as 3 millicuries at one time) as well as ¹²⁵I (100 µCi), ³H (1 mCi), and ¹⁴C (100 µCi). He has completed radiation safety training at several institutes since 1989, including Yale University. Dr. Neufer has been with The John B. Pierce Laboratory since 1996 and has been serving as the RSO since July of 2002. He is an Associate Fellow at Pierce and an Associate Professor in the Cellular & Molecular Physiology Department at Yale University. Dr. Neufer has the full authority and support of the John B. Pierce Laboratory to perform the necessary duties of RSO, including halting any laboratory procedure involving radioactivity that he deems unsafe, as well as performing annual inspections, record keeping, etc.*

Authorized Users (name, total quantity of isotope permitted in lab, experience)

- **P. Darrell Neufer, Ph.D.** - ³²P (1 mCi), ¹²⁵I (1 mCi), ³H (5 mCi), and ¹⁴C (1 mCi) – experience listed above.
- **Nina Stachenfeld, Ph.D.** - ³²P (1 mCi), ¹²⁵I (1 mCi), ³H (5 mCi), and ¹⁴C (1 mCi) - Dr. Stachenfeld received her Ph.D. in Physiology in 1993 and is currently an Assistant Fellow at The John B. Pierce Laboratory and an Assistant Professor in Epidemiology & Public Health and Obstetrics, Gynecology and Reproductive Sciences, Yale University. She has completed radiation safety training at Yale University and has been working with radioactivity in her research since 1993 without incident.

- **James Douglas, Ph.D.** - ^{32}P (1 mCi), ^{125}I (1 mCi), ^3H (5 mCi), and ^{14}C (1 mCi) – Dr. Douglas received his Ph.D. in Pharmacology in 1967 and is currently a Fellow at The John B. Pierce Laboratory and Senior Research Scientist and Lecturer in Epidemiology & Public Health and Obstetrics, Gynecology and Reproductive Sciences, Yale University. He served as RSO for >10 years prior to Dr. Neuffer, has completed radiation safety training at Yale University and has been working with radioactivity in his research since 1967 without incident.

Item 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)

Groups of workers - Potential occupationally exposed individuals include Research Assistants (technicians), Undergraduate and Graduate Students, and Post-Doctoral Fellows and Associates working in the laboratories of the Principal Investigators listed under Item 7. Other personnel (ancillary), including building maintenance and office staff, that do not work directly with radioactivity but may occasionally frequent restricted areas also receive general radiation safety training as described below.

Radiation Safety Training Program – All personnel working in a laboratory approved for radioactive use are required to complete radiation safety training through the Yale University Office of Environmental Health and Safety. This is a mandatory course for personnel working with radioactive material or frequenting an area where radioactive materials are stored or used. Topics covered include: types and characteristics of radioactivity encountered in biomedical research; safe laboratory practices for handling and working with radioactivity, personal and work area monitoring and surveying; record keeping; purchasing receiving and shipping radioactivity; emergency procedures, etc. The Pierce Laboratory receives written confirmation of completion of training from Yale University OEHS. In addition, Principal Investigators (or their experienced designees) provide radiation safety training specific to their individual labs, including safe practices for protocols using radioactivity, storage, monitoring, record keeping, etc. *All laboratory personnel working with radioactivity receive refresher training from their Principal Investigator and through an instructional video on an annual basis. Radiation safety training through Yale may be repeated at any time deemed appropriate by the P.I. and/or the laboratory personnel (e.g., several years since working with radioactivity).* Ancillary personnel receive general radiation safety training on an annual basis through an instructional video.

Item 9. FACILITIES AND EQUIPMENT

The John B. Pierce Laboratory is a 38,000 square foot building comprising ~15 biomedical research laboratories, technical support facilities and offices. Research involving radioactive material is conducted in three laboratories (see attached diagrams). A full description of the area(s) assigned for the receipt, storage, security, preparation and measurement of radioactive materials follows:

Receipt – Radioactive material is delivered to the receiving room of The John B. Pierce Laboratory. Receiving room staff are trained to identify packages containing radioactive material (labels on box and/or shipping manifests). These orders are placed in a secure secondary container designated for “radioactive material”. The principal investigator, an individual within the PI’s laboratory (e.g., designee) and the RSO are immediately notified

electronically (email) of the delivery. The PI's laboratory is then required to retrieve the package, *wearing appropriate gloves*, and take it to the respective laboratory. Packages not collected within 3 hours of delivery to the receiving room will be removed and held by the RSO for the PI.

Storage – All radioactive material is stored in the original shipping containers in a designated and locked secondary container (i.e., room or lock box) in the PI's laboratory. Secondary containers are housed in a refrigerator or freezer when required for storage of the material (i.e., ^{32}P -dATP).

Security – The John B. Pierce Laboratory is a 24h/d restricted access facility. During business hours (M-F, 8:30 am – 5:00 pm), public entry is granted electronically by a receptionist through two entrances visible to the receptionist. Electronic access through all other entrances is limited (via electronic key) to employees and graduate students only. Each keyed entry is automatically logged on a central computer. As stated above, radioactive material is stored in secondary locked containers within the PI's laboratory.

Preparation/use – Laboratories approved for radioactive use contain designated solid nonporous bench top areas (workstations) restricted exclusively to radioactive work. All work areas are double protected through use of plastic work trays and absorbent bench paper to limit potential contamination of liquid spills. These areas house appropriate shielding equipment ($\frac{3}{4}$ inch transparent Plexiglas workstation boxes w/doors, Plexiglas or lead shields, tube racks, etc.) for conducting experiments and storing liquid and/or solid waste material (primary containers contained in secondary $\frac{3}{4}$ inch Plexiglas box w/lid containers or placed behind lead shielding). No volatile materials are used. All liquid and solid waste containers are appropriately labeled indicating the isotope and activity.

Measurement – Measuring equipment currently includes a Beckman LS 3801 counter and a Packard Instruments Cobra Gamma Counter.

Item 10. RADIATION SAFETY PROGRAM

1. *Audit Program* – The RSO conducts an annual audit of the Pierce Laboratory Radiation Safety Program according to NRC guidelines and maintains records of these audits and other reviews of program content and implementation for three (3) years from the date of the record. Records of these audits include the following information: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

2. *Radiation Monitoring Instruments* - Each laboratory is also equipped with a handheld survey meter designed to detect alpha or beta emissions (pancake type GM tube) or gamma emission (energy compensated GM probe). For ^{125}I , a low energy gamma scintillation detector is used. We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary.

3. *Material Receipt and Accountability* –

Receipt – Details regarding notification of PI upon receipt of radioactive material are provided under Item 9. Once the package is brought into the PI's laboratory, it is inspected

by the receiver (while wearing gloves) for damage or leaks on both the exterior and, after opening, interior surfaces. Although nearly all packages received by the laboratory contain radiation quantities less than Type A quantity (as defined in Appendix A of section 71.4), laboratory personnel are instructed to perform wipe tests on the exterior and interior surfaces of the box and record the results in the laboratory radiation records log. Radioactive material is then placed in designated secure storage.

Accountability - The Pierce Laboratory uses a computer program for all purchase requisitions. All orders for radioactive material are entered into the computer system by the individual user or the PI placing the order. The system is designed such that each order must be received electronically by the PI and approved by the RSO before a purchase requisition is placed. Once the order is received, the individual user or PI is required to enter this information into the system, serving to log the material as present in the building and alerting the accounting staff that the item is clear to be paid. Individual users are also required to log receipt of the material in a laboratory notebook, noting the isotope, activity, volume/amount, chemical form, and the date. Each use of the isotope is subsequently logged on the same sheet, noting the date, activity used, manner of disposition, and the activity remaining. Final disposition of the radioactive material is logged electronically into the accounting system by the individual user (noting the manner of disposal) with notification automatically sent to the PI and the RSO. This system ensures that the RSO is notified of all radioisotope orders, transfers and disposals and provides immediate accessibility and accountability for radioactive material in the building for any selected period of time. Only the Director of the Laboratory, the RSO, and the Business Manager have access to this account for review. Physical inventories will be conducted at intervals not to exceed 6 months to account for all sealed sources and devices received and possessed under the license.

4. **Occupational Dose** - We have done a prospective evaluation (personal dosimetry for >5 years) and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20.

5. **Public Dose** - NA. No airborne, waterborne, or external radioactive exposure is emitted by the Pierce Laboratory. It is currently the policy of Pierce Laboratory not to dispose of any liquid radioactive waste in laboratory sinks or the sewer system.

6. **Safe Use of Radionuclides and Emergency Procedures** - Procedures for safe use, including security of materials, and emergencies have been developed. An "Emergency Response Plan" is not required for this license, pursuant to 10 CFR 30.32(i). Permission is requested to revise procedures only if 1) the changes are reviewed and approved by the licensee management and the RSO in writing; 2) the licensee staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the NRC regulations and the license; and 4) the changes do not degrade the effectiveness of the program.

7. **Surveys** - Each day radioactivity is used, individual users are required to conduct survey meter scans at the conclusion of the experiment on themselves (personal survey scan on lab coat, hands, arms, etc.) and on the work area surfaces (bench paper, shielding material, laboratory equipment, etc.). The results of each survey are recorded on log sheets located in a laboratory

radioactive material notebook. *For work involving H^3 , C^{14} , and I^{125} , wipe tests will be conducted at the conclusion of the experiment within the work area to insure that low level contamination is not present.* Should surface contamination be found, individual users are required to clean (Radiac wash) and/or dispose (bench paper) of the contaminated material, using the appropriate radioactive waste container. In addition, wipe test surveys are conducted on pre-designated potential hotspots (each laboratory has a set diagram) within both the restricted and unrestricted areas once per week for any week in which radioactive material is used. Counts (printouts) from each test are placed in the laboratory radioactive material notebook. Similar clean-up procedures are implemented should any contamination be found.

8. *Transportation* – The Pierce Laboratory is in compliance with NRC and U.S. Department of Transportation (DOT) regulations.

9. *Minimization of Contamination* – Please refer to the following sections: "Radioactive Material - Unsealed and/or Sealed Sources," "Facilities and Equipment," "Radiation Safety Program - Safe use of Radioisotopes and Emergency Procedures," "Radiation Safety Program - Surveys," and "Radiation Safety Program - Waste Management."

Item 11. WASTE MANAGEMENT PROGRAM

We will use the model waste procedures published in Appendix T to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.