

Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C.

1000 U.S. Highway 202, P.O. Box 300
Raritan NJ 08869

J-6

September 18, 2008

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Sir or Madam:

03010814


This is a request by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. in Raritan, NJ to amend its NRC Material License number 29-02608-03 to reflect a change in the Radiation Safety Officer from Curtis Smock to James Kwiatkowski.

Please find attached two copies of NRC Form 313 Application for Materials License and Mr. James Kwiatkowski's CV pertaining to radioactive materials experience.

In addition, all correspondence related to this license and the radiation safety program at Johnson & Johnson Pharmaceutical Research & Development, L.L.C. in Raritan, NJ should be directed to Mr. James Kwiatkowski, Manager - Environmental, Health & Safety.

If there are any questions regarding this, please contact James Kwiatkowski at (908) 704-4930.

Sincerely,



Kirk Huber
Sr. Director Operations & Process Quality
Johnson & Johnson Pharmaceutical
Research & Development, L.L.C.

<p>NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION</p> <p>(4-2008) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40</p> <p style="text-align: center;">APPLICATION FOR MATERIALS LICENSE</p>	<p>APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008</p> <p>Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollections@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NIOS-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</p>
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INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p>DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20565-0001</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN:</p> <p>ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:</p> <p>LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 476 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415</p>	<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2449 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4362</p> <p>ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:</p> <p>NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 812 E. LAMAR BOULEVARD, SUITE 400 ARLINGTON, TX 78011-4125</p>
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PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>29-02608-03</u></p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p> <p>James Kwiatkowski J&J Pharmaceutical Research & Development, L.L.C. 1000 Route 202 Raritan, NJ 08869</p>
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<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>Johnson & Johnson Pharmaceutical Research & Development, L. L. C. 1000 Route 202 Raritan, NJ 08869</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>James Kwiatkowski</p> <hr/> <p>TELEPHONE NUMBER</p> <p style="text-align: center;">(908) 704-4930</p>
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SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

<p>6. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>8. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>				
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>	<p>9. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>				
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>				
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSE FEES (See 10 CFR 170 and Section 170.31)</p> <table style="width:100%;"> <tr> <td style="width:70%;">FEE CATEGORY</td> <td style="width:30%;">AMOUNT ENCLOSED</td> </tr> <tr> <td></td> <td style="text-align: center;">5</td> </tr> </table>	FEE CATEGORY	AMOUNT ENCLOSED		5
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13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</p> <p>Kirk Huber - Sr. Director Oper. & Process Quality</p>	<p>SIGNATURE</p> <p><i>[Signature]</i></p>	<p>DATE</p> <p>18 Sep 08</p>
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FOR NRC USE ONLY


TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
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APPROVED BY				DATE	

US NRC License No. 29-02608-03 Amendment**September 18, 2008****Johnson & Johnson Pharmaceutical Research & Development, L.L.C.****Raritan, NJ****ITEM: NO. 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE:**

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. has appointed James Kwiatkowski as the Radiation Safety Officer replacing Curtis Smock, who has resigned from Johnson & Johnson. Mr. Kwiatkowski currently serves as Manager of Environmental, Health & Safety for Johnson & Johnson Pharmaceutical Research & Development, L.L.C. in Raritan, NJ. Mr. Kwiatkowski has been employed by Johnson & Johnson for 7 years, during which time he has been responsible for various aspects of the radiation safety programs across three NRC licenses, including the radiation safety officer role for Johnson & Johnson Consumer Product Company from 2002 – 2003.

Attached please find Mr. Kwiatkowski's CV.

Attachment I – Curriculum Vitae

JAMES T. KWIATKOWSKI
Manager – Environmental, Health & Safety
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
1000 Route 202
Raritan, NJ 08869
(908) 704-4930


EDUCATION:

University of Medicine & Dentistry of New Jersey (UMDNJ), Piscataway, NJ
MPH Environmental & Occupational Health, October 2001

Rutgers University, Cook College, New Brunswick, NJ
B.S., Environmental Science/Pollution & Treatment Sciences, May 1997

EXPERIENCE:

Manager, Environmental, Health & Safety – Johnson & Johnson Environmental, Health & Safety supporting Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (2/07 – present).

- Assistant Radiation Safety Officer for the site supporting approximately 40 laboratories and two radioactive waste storage areas utilizing/storing millicurie quantities of a variety of beta and gamma emitting materials (primarily H-3, C-14, Fe-59)
- Providing technical advice and guidance regarding procedures and practices for safe handling of radioactive materials, radiation-producing equipment, lasers and other sources of non-ionizing radiation.
- Providing ionizing and non-ionizing radiation safety training to users to ensure guidance in safe handling for a variety of beta and gamma emitting radioactive materials, ionizing radiation equipment and various lasers and non-ionizing radiation producing equipment.
- Coordinate radioactive waste collection, storage, decay-in-storage and off-site shipment programs for waste streams containing H-3, C-14 and Fe-59.

Staff Industrial Hygiene Specialist – Johnson & Johnson Safety & Industrial Hygiene supporting Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (8/06 – 2/07).

- Assistant Radiation Safety Officer for the site supporting approximately 40 laboratories and two radioactive waste storage areas utilizing/storing millicurie quantities of a variety of beta and gamma emitting materials (primarily H-3, C-14, Fe-59)

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

- Providing technical advice and guidance regarding procedures and practices for safe handling of radioactive materials, radiation-producing equipment, lasers and other sources of non-ionizing radiation.
- Providing ionizing and non-ionizing radiation safety training to users to ensure guidance in safe handling for a variety of beta and gamma emitting radioactive materials, ionizing radiation equipment and various lasers and non-ionizing radiation producing equipment.
- Coordinate radioactive waste collection, storage, decay-in-storage and off-site shipment programs for waste streams containing H-3, C-14 and Fe-59.

Sr. Industrial Hygiene Specialist – Johnson & Johnson Safety & Industrial Hygiene supporting Johnson & Johnson Pharmaceutical Research & Development, L.L.C (7/04 – 8/06).

- Assistant Radiation Safety Officer for the site supporting approximately 100 laboratories and two radioactive waste storage areas utilizing/storing millicurie quantities of a variety of beta and gamma emitting materials (primarily H-3, C-14, P-33, P-32, Fe-59, I-125 and S-35).
- Providing technical advice and guidance regarding procedures and practices for safe handling of radioactive materials, radiation-producing equipment, lasers and other sources of non-ionizing radiation.
- Manage radioactive materials receipt, inventory, waste management and records maintenance programs.
- Supervising quarterly/monthly monitoring utilizing liquid scintillation counting systems, gamma counting systems and a variety of portable survey instruments for approximately 100 laboratories and 2 waste storage areas utilizing/storing millicurie quantities of a variety of beta and gamma emitting materials.
- Providing ionizing and non-ionizing radiation safety training to users to ensure guidance in safe handling for a variety of beta and gamma emitting radioactive materials, ionizing radiation equipment and various lasers and non-ionizing radiation producing equipment.
- Coordinate radioactive waste collection, storage, decay-in-storage and off-site shipment programs for waste streams containing H-3, C-14, P-32, P-33, S-35, Fe-59, Ca-45 and I-125.

Industrial Hygiene Specialist – Johnson & Johnson Safety & Industrial Hygiene supporting Johnson & Johnson Pharmaceutical Research Institute, Raritan, NJ, Ortho-Clinical Diagnostics Inc., Raritan, NJ and Johnson & Johnson Consumer Products Companies, Skillman, NJ (8/01 – 7/04).

- Radiation Safety Officer for Johnson & Johnson Consumer Products Companies. Provide technical advice and guidance regarding procedures and practices for safe handling of radioactive materials, radiation-producing equipment, lasers and other sources of non-ionizing radiation. Manage radioactive materials receipt, inventory, waste management and records maintenance programs.
- Assuring compliance with all elements of state and federal government issued radioactive materials licenses.

- Providing ionizing and non-ionizing radiation safety training to users to ensure guidance in safe handling for a variety of beta and gamma emitting radioactive materials, ionizing radiation equipment and various lasers and non-ionizing radiation producing equipment.
- Supervising quarterly/monthly monitoring utilizing liquid scintillation counting systems, gamma counting systems and a variety of portable survey instruments for approximately 100 laboratories and two radioactive waste storage areas utilizing/storing millicurie quantities of a variety of beta and gamma emitting materials.
- Perform thyroid scans and evaluations for employees working with I-125 and performing iodinations.
- Coordinate radioactive waste collection, storage, decay-in-storage and off-site shipment programs for waste streams containing H-3, C-14, P-32, P-33, S-35, Fe-59, Ca-45 and I-125.
- Attend quarterly radiation safety committee meetings.
- Calibrate portable radiation detection instrumentation, liquid scintillation counting systems and gamma counting systems utilizing Cs-137, I-125, I-129, H-3, C-14 and Sr-90 sources.
- Evaluate incoming and outgoing radioactive materials with wipe testing and dose rate evaluation for packages containing site authorized radioactive materials.
- Coordinate distribution, collection, maintenance and evaluation of personnel dosimetry program.

Health & Safety Specialist – Rutgers Environmental Health & Safety, Piscataway, NJ (9/99 – 8/01).

- Conducted quarterly monitoring of approximately 100 laboratories using up to millicurie amounts of C-14, H-3, S-35, P-32, P-33 and I-125.
- Performed annual contamination surveys in approximately 100 laboratories utilizing liquid scintillation counting systems and a variety of portable survey instruments for detecting beta and gamma emitting materials.
- Participated on an emergency response team to handle radioactive and chemical spills/emergencies.

Radiation Safety Specialist – Rutgers Environmental Health & Safety, Piscataway, NJ (10/98 – 9/99).

- Presented radiation safety training to lab personnel employed by Rutgers University and Robert Wood Johnson Medical School to ensure safe handling of the following radioisotopes: P-32, P-33, S-35, H-3, C-14, Cr-51, I-125 and Ca-45.
- Coordinated radioactive waste collection, storage, decay-in-storage and off-site shipment programs for waste streams containing P-32, P-33, S-35, H-3, C-14, Cr-51, I-125 and Ca-45. Sampled and surveyed radioactive waste held for decay-in-storage to ensure compliance with federal, state and local regulations.
- Conducted quarterly audits of the radioactive waste storage facility utilizing liquid scintillation counting systems and a variety of portable survey instruments.

- Continued responsibilities of a Radiation Safety Technician.

Radiation Safety Technician – Rutgers Environmental Health & Safety, Piscataway, NJ (10/97 – 10/98).

- Picked-up millicurie amounts of H-3, C-14, P-32, P-33, S-35, I-125, Cr-51 and Ca-45 waste from all radioactive materials-use laboratories at Rutgers University and Robert Wood Johnson Medical School. All radioactive waste was transported to a storage facility on Busch Campus following NRC and DOT regulations.
- Conducted quarterly audits of the radioactive waste storage facility utilizing liquid scintillation counting systems and a variety of portable survey instruments.
- Coordinated radioactive waste storage, decay-in-storage and preparation of containers for off-site shipment programs for waste streams containing H-3, C-14, P-32, P-33, S-35, I-125, Cr-51 and Ca-45. Sampled and surveyed radioactive waste held for decay-in-storage to ensure compliance with federal, state and local regulations.
- Maintained up-to-date inventory on all waste being generated and disposed utilizing HPA computer program.
- Developed and updated Standard Operating Procedures (SOP) to be followed while working with radioactive waste.

TRAINING:

DOT Training Requirements for Shipping & Receiving Radioactive Materials – University of Medicine & Dentistry of NJ (UMDNJ), Newark, NJ 2003.

Radiation Safety Annual Refresher Training – J&J Pharmaceutical Research & Development, L.L.C., Raritan, NJ, 2002-2007.

Radiation Safety Officer – CSI Radiation Safety Academy, Gaithersburg, MD, 2001 (40 hours)

DOT Training Requirements for Shipping & Receiving Radioactive Materials – CSI Radiation Safety Academy, Gaithersburg, MD, 2001.

Radiation Safety Orientation Training – R. W. Johnson Pharmaceutical Research Institute, Raritan, NJ, 2001 (4 hours).

DOT Hazmat Employee Training – Clean Harbors Environmental Training Specialists, 2000 (8 hours).

Liquid Scintillation Counting – Cook College Department of Environmental Sciences and the Eastern Regional Radon Training Center, Piscataway, NJ, 1999.

Basic Radioisotope Theory – Cook College Department of Environmental Sciences and the Eastern Regional Radon Training Center, Piscataway, NJ, 1999.

Radiation Instrumentation – Cook College Department of Environmental Sciences and the Eastern Regional Radon Training Center, Piscataway, NJ, 1999.

Radioactive Waste Packaging, Transportation and Disposal Workshop – Chem-Nuclear Systems, Columbia, SC, 1998 (40 hours).

Annual Radiation Safety Training – Rutgers University, Piscataway, NJ, 1998-2001.

Hazardous Waste Site Operations Refresher – Clean Harbors Environmental Training Specialists, 1998-2001 (8 hours).

Radiation Safety Orientation Training – Rutgers University, Piscataway, NJ, 1997 (4 hours)

DOT Hazardous Materials Transportation Regulations Training – University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, New Jersey/New York Hazardous Materials Worker Training Center, 1997 (8 hours).

Hazardous Materials Incident Response Operations – U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Edison, NJ, 1996 (40 hours).

PROFESSIONAL ORGANIZATIONS:

- New Jersey American Industrial Hygiene Association (2006 – present)
- American Industrial Hygiene Association (2000 – present)