



March 17, 2015

Ms. Patricia Pelke
Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: License Number 24-17450-01
Docket Number 030-12559

Dear Ms. Pelke

This letter constitutes a request for an amendment to Broad Scope Material License 24-17450-01. This license is issued to Mallinckrodt LLC to cover Research and Development activities at its Hazelwood, MO location. The purpose of this amendment request is to allow the appointment of Mr. James R. Schuh as Radiation Safety Office (RSO). Included with this letter is a completed NRC Form 313 (Attachment I), a copy of Mr. Schuh's resume (Attachment II), a signed delegation of authority from the Sr. Director of Research and Development (Attachment III), Mr. Schuh's acknowledgement of his responsibility as RSO (Attachment IV) and an organization chart (Attachment V).

Mr. Schuh was hired by Mallinckrodt in January, 1998 as Supervisor of Health Physics and Radiation Safety Officer for our Maryland Heights manufacturing facility. He has held positions of increasing responsibility with Mallinckrodt since that time. He served as Manager of EHS at the Maryland Heights facility and as Manager of EHS for Mallinckrodt's 39 nuclear pharmacies. Jim is currently the Director, EHS – Nuclear Operations with oversight responsibilities for Mallinckrodt EHS programs at all of our facilities that utilize radioactive materials and radiation producing machines.

Prior to joining Mallinckrodt, Mr. Schuh served as the Assistant Manager of Health Physics at the University of Missouri Research Reactor (MURR). At MURR Mr. Schuh was responsible for all aspects of operational health physics for this 10 MW research reactor as well as for the R&D performed at the reactor facility.

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During our phone conversation on March 13, 2015 you requested that we include additional information on Mr. Schuh's responsibilities and how adequate oversight would be maintained at both the Maryland Heights plant as well as the Hazelwood R&D facility. This information is included in the following paragraphs.

While there has been turnover at the RSO position at Maryland Heights over the past few years, there continues to be significant experience at both the professional level as well as at the technician level. The three Health Physicists reporting into the RSO have a combined 35 years of experience at the Maryland Heights facility. In addition, the current Production Manager for our Cyclotron Hot Products production area previously served as the Health Physics Supervisor and then the Manager of EHS for the Maryland Heights plant. Finally, the five Health Physics Technicians have a combined 74 years of experience at the Maryland Heights facility.

In addition, Mr. Schuh will continue to have a significant presence at the Maryland Heights plant. He maintains an office at the plant; he has weekly meetings with the RSO and routinely participates in the Site Director's staff meeting. He also continues to serve as Chairperson for the Radiation Safety Committee required under the Maryland Heights Broad-Scope license.

We believe that this extensive experience at Maryland Heights as well as the significant experience gained by the Maryland Heights RSO (while working for other employers) provides adequate oversight of the Radiation Safety Program for our Maryland Heights plant.

Similarly, the experience of radiation safety staff at the Hazelwood site is also extensive. The two individuals who report into the RSO have a combined 32 years of experience in radiation safety at the Hazelwood facility. Mr. Schuh has participated in the facilities' radiation safety committee meetings for the last five years and routinely conducted the annual program review of the Radiation Protection Program for the site. As a result, he has a good working knowledge of the program and people, and will not have the steep learning curve that normally comes with becoming a Radiation Safety Officer on a new license or at an unfamiliar site.

Mr. Schuh will also maintain his office in our Hazelwood facility and will split his time between Hazelwood and Maryland Heights. The division of time will be flexible and based upon the activities at each location at any given time.

I trust this information will adequately address the concern expressed during our March 13th phone call. I appreciate your concern and will closely monitor the oversight provided to the Hazelwood site. I have also reached out to Dale Eyman (Site Director at Maryland Heights) to ensure that he closely monitors the oversight of the program at Maryland Heights as well.

I appreciate your attention to this license amendment request. If you have any questions, please do not hesitate to contact me at (314) 654-3363 or Mr. Schuh at (314) 654-7981.

Sincerely,

A handwritten signature in cursive script, appearing to read "R. A. Roberts".

Richard A. Roberts
Sr. Director Research and Development

JS:rr
Attachments

cc: File
Eric Berry (via E-mail)
Dale Eyman (via E-mail)
Alan Faust (via E-mail)
Michael Giuliani (via E-mail)
Jim Schuh (via E-mail)

NRC FORM 313
(03-2014)
10 CFR 30, 32, 33, 34
35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION



APPLICATION FOR MATERIALS
LICENSE

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 05/31/2015

Estimated burden per response to comply with this mandatory collection request: 4.3 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 FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-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.

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. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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IF YOU ARE LOCATED IN:

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:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
- ☒ B. AMENDMENT TO LICENSE NUMBER 24-17450-01
- ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Mr. James Schuh
Mallinckrodt LLC
675 McDonnell Blvd.
Hazelwood, MO 63042

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

675 McDonnell Blvd.
Hazelwood, MO 63042

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James R. Schuh

BUSINESS TELEPHONE NUMBER

(314) 654-7981

BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

James.Schuh@Mallinckrodt.com

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.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)

FEE CATEGORY

AMOUNT
ENCLOSED \$

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, 37, 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.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

Richard A. Roberts, Ph.D., Sr. Director

SIGNATURE

R. A. Roberts

DATE

17 Mar 2015

FOR NRC USE ONLY

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

Attachment II

Mallinckrodt, LLC
675 McDonnell Blvd.
Hazelwood, MO 63042
(314) 654-7981

James R. Schuh

EDUCATION

University of Phoenix
Master of Business Administration, 2006
University of Missouri - Columbia
M.S. Nuclear Engineering (Health Physics), 1994
B.S. Mechanical Engineering, 1985

CERTIFICATION

Certified Health Physicist American Board of Health Physics, 1995, Currently Inactive.

EXPERIENCE

Mallinckrodt LLC

January 1998 to Present

Director, EHS – Nuclear Operations
Radiological Programs Director
Manager, Environmental, Health and Safety and Radiation Safety Officer
Manager, Health Physics and Radiation Safety Officer
Supervisor, Health Physics and Radiation Safety Officer

Responsible for oversight of radiological operations at all Mallinckrodt locations that possess radioactive materials or radiation producing machines. These include Nuclear Medicine manufacturing facilities in the United States and Europe, 38 Nuclear Pharmacies and 4 Co-60 irradiators use for Sterilization of medical products.

Responsible for developing, implementing and managing a comprehensive radiation protection program at this major radiopharmaceutical manufacturing facility. Responsible for ensuring compliance with state and federal regulatory requirements associated with the manufacture and distribution of radioactive drug products. Responsible for all management aspects of the radiation safety and waste management programs including technical administration, budget and fiscal affairs, selection and training of personnel, and project management. This facility utilizes kCi quantities of radioactive material on a weekly basis for manufacturing diagnostic and therapeutic radiopharmaceuticals.

University of Missouri - Columbia Research Reactor

August 1984 to January 1998

Assistant Manager, Reactor Health Physics
Health Physicist
Sr. Research Specialist
Research Specialist
Student Assistant

Assist in the management of a radiation safety program for a 10 MW research reactor and all work performed under three materials licenses at the Reactor Center. Serve as Deputy Radiation

Safety Officer for a Type A Broad Scope License. Supervise professional and technical staff and direct their work. Responsible for planning and monitoring reactor maintenance evolutions, hot cell operations, glove box operations, shipment of radioactive materials and managing program for radioactive and mixed wastes. Audit programs to ensure compliance with applicable licenses, regulations and internal policies. Review radioactive material utilization requests and new project applications. Assist in the design of new facilities and equipment. Review proposed modifications of existing facilities. Perform safety analyses to support Reactor Utilization Requests, Respond to researcher inquiries regarding the utilization of radioactive materials. Train individuals in the theory and practice of radiation safety and the use of radioactive materials. Serve on appropriate committees. Respond to radiological emergencies and direct recovery activities.

Responsible for all aspects of an Exempt Release (Part 32) License Quality Assurance Program. Implement program in accordance with Standard Operating Procedures. Review analyses and supporting data to determine suitability of material for release. Review Standard Operating Procedures and recommend revisions. Train analysts associated with the Exempt Release Program. Direct or perform research to expand the envelope of material releasable under the License.

Responsible for all aspects of Reactor Chemistry. Direct or perform analysis of environmental samples, bioassay samples, gemstones, pool and primary coolant, stack effluents, liquid effluents, solid waste, continuous air monitor filters and other samples as required. Maintain calibrations of stack gas, particulate, and iodine monitors. Assists in preparing safety analyses as part of reactor utilization requests. Develop and review Standard Operating Procedures and Internal Guides. Train individuals in theory and operation of radiation detection instrumentation.

TRAINING

Health Physics Society Summer School. Management and Administration of Radiation Safety Programs. Participated in a week long training course covering all aspects of the management of large radiation safety programs including state and federal regulatory considerations, licensing, and ISO management of radiation safety programs.

Fire Department Incident Command Training. Participated in a training course covering the command structure of emergency response organizations when responding to large incidents. The course provided an in-depth review of the interaction of site, fire department, police department, and medical personnel to major incidents.

Nevada Test Site. Participated in a two week Radiological Emergency Response training course. The course consisted of classroom work and practical exercises. Areas covered included transportation accidents, on-site and off-site response to a nuclear power reactor accident and general laboratory accident response.

Brookhaven National Laboratory. Health Physics Training Program. Participated as a Technical Collaborator in this comprehensive 10 week training program in applied Health Physics.

Callaway Nuclear Power Station. Spent 10 weeks observing the Health Physics requirement of all operating nuclear reactor. Areas covered included quality assurance, dosimetry, job coverage, effluent management and emergency preparedness.

PROFESSIONAL AFFILIATIONS

American Association of Safety Engineers
Health Physics Society
Missouri Nuclear Emergency Team (MoNET), Emergency Management Agency, Office of Adjutant General, Missouri Department of Safety

Attachment III

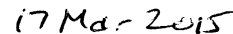
Delegation of Authority for Radiation Safety Officer

James Schuh has been appointed Radiation Safety Officer (RSO) and is responsible for ensuring the safe use of radioactive material. The RSO is responsible for managing the radiation safety program; identifying radiation safety concerns; initiating, recommending, or providing correction action; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.



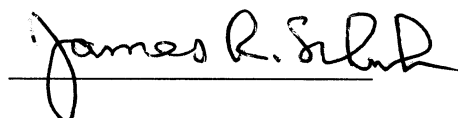
Richard Roberts
Sr. Director, Research and Development



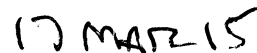
Date

Attachment IV**Acceptance of Responsibility for Radiation Safety Officer**

I have successfully completed education, training and experience sufficient to serve as Radiation Safety Officer for license 24-17450-01 issued to Mallinckrodt LLC for Research and Development activities at its Hazelwood, Missouri location. This includes training and experience in radiation safety, regulatory issues, emergency procedures and specific license conditions associated with the uses covered by the license listed above. I accept responsibility for insuring the safe use of radioactive material; managing the radiation safety program; identifying radiation safety concerns; initiating, recommending or providing corrective actions; verifying implementation of corrective actions; and insuring compliance with regulations for the use of radioactive materials.



James R. Schuh
Director, EHS – Nuclear Operations

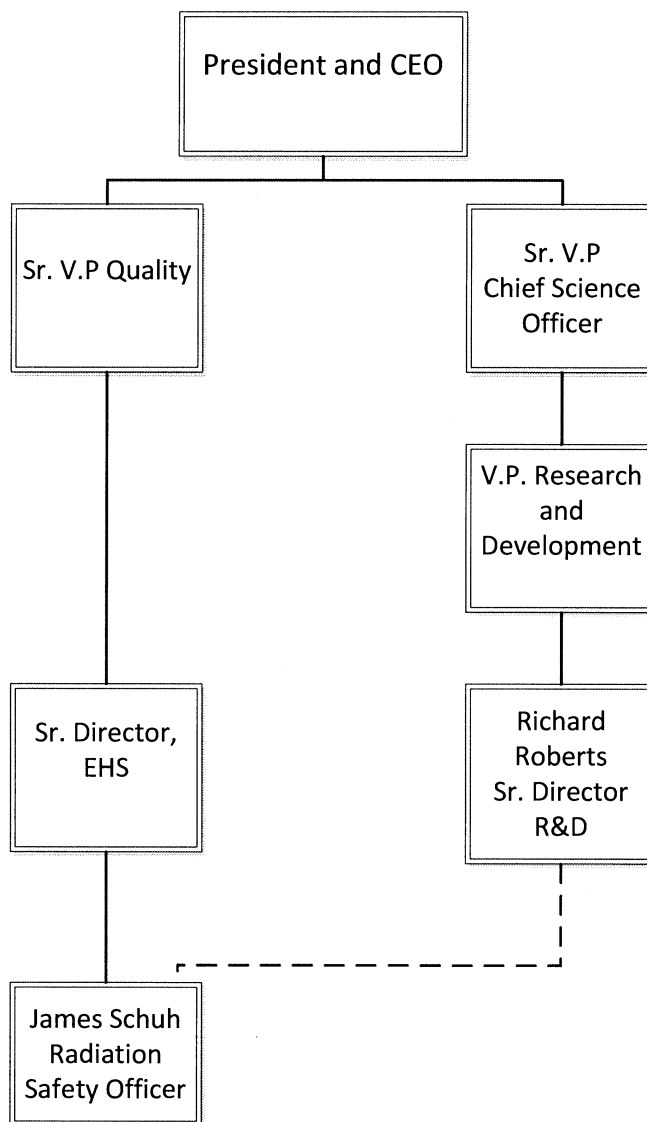


Date

Attachment V
Organizational Structure

License 24-17450-01

March 17, 2015



From: (314) 654-3763
Reonda Hunt CO User Support
MALLINCKRODT LLC
675 McDonnell Blvd
User Support B-20
Hazelwood, MO 63042

Origin ID: ALNA



Ship Date: 17MAR15
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BILL SENDER

Ms. Patricia Pelke
U.S. Nuclear Regulatory Commission
2443 Warrenville Road Ste 210

LISLE, IL 60532

Ref # 011010080108
Invoice #
PO #
Dent #

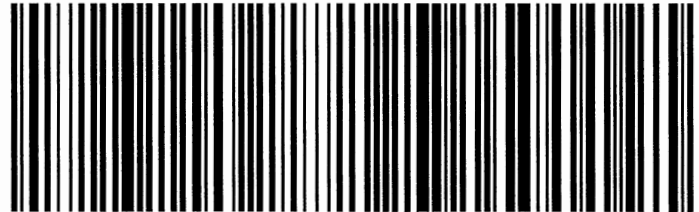
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