



**sanofi aventis**

Br. 2

July 25, 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

03008963

REF: sanofi-aventis U.S. Inc. – Amendment License Number 29-15354-01

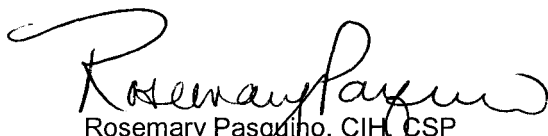
Dear Sir or Madame,

Enclosed please find two copies of an amendment application for sanofi-aventis U.S. Inc., Material License 29-15354-01. We are requesting a change in the Radiation Safety Officer assignment, from Rosemary Pasquino to Michael Laemmerhirt.

As noted in the attached documents, Michael has over 10 years of experience in radiation safety and has assisted with implementation of the Bridgewater site programs for the past 7 years. Michael is attending Radiation Safety Officer Training during the week of July 21<sup>st</sup>, 2008, in order to ensure that he has the most current information regarding the management of a radiation safety program. Michael reports to me and I report to the Administrative Site Director, Thomas Metcalf, VP, Administration & Resources, as shown in Attachment 2. Once we have your approval, a Delegation of Authority announcement (attachment 3) will be issued to the site.

Please contact me at 908-231-4933 or via e-mail at <mailto:Rosemary.Pasquino@aventis.com> if there are any questions about this application.

Sincerely,

  
Rosemary Pasquino, CIH, CSP  
Director HSE/Radiation Safety Officer

Cc: Thomas Metcalf  
Michael Laemmerhirt

RECEIVED  
REGION 1

2008 JUL 28 PM 12:10

<b>NRC FORM 313</b> (4-2008) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	<b>APPROVED BY OMB: NO. 3150-0120</b> 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 <a href="mailto:infocollects@nrc.gov">infocollects@nrc.gov</a> , 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.
<b>APPLICATION FOR MATERIALS LICENSE</b>		
<b>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.</b>		
<b>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b>  DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001  <b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</b>  <b>IF YOU ARE LOCATED IN:</b>  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 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415		<b>IF YOU ARE LOCATED IN:</b>  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 612 E. LAMAR BOULEVARD, SUITE 400 ARLINGTON, TX 76011-4125
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)  <input type="checkbox"/> A. NEW LICENSE <input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>29-15354-01</u> <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)  <b>sanofi-aventis U.S. Inc.</b> <b>1041 Route 202-206</b> <b>PO Box 6800</b> <b>Bridgewater, NJ 08807</b>	
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED  <b>1041 Route 202-206</b> <b>Bridgewater, NJ 08807</b>	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION  <b>Rosemary Pasquino</b>  TELEPHONE NUMBER  <b>(908) 231-4933</b>	
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 (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, 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 <b>Thomas Metcalf, VP Administration &amp; Resources</b>	SIGNATURE _____ 	DATE <b>25 JULY 2008</b>
<b>FOR NRC USE ONLY</b>		
TYPE OF FEE	FEE LOG	FEE CATEGORY
APPROVED BY	DATE	COMMENTS

Attachment 1

Amendment Application – License Number 29-15354-01

sanofi-aventis U.S. Inc.

Route 202-206 North

Bridgewater, NJ 08807

5. RADIOACTIVE MATERIAL TO BE POSSESSED: No change
6. PURPOSE(S) FOR USE OF LICENSED MATERIAL: No change
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY AND THEIR TRAINING EXPERIENCE:

Radiation Safety Officer – Michael K. Laemmerhirt (Manager, HSE)

Training/Certifications:

B.S. Biology, Montclair State College, Upper Montclair NJ

Certified Safety Professional, Board of Certified Safety Professionals

Basic Radiological Health, UTHSA, February 8-12, 1988

Advanced Radiological Health, UTHSA, May 8-12, 1989

Radiation Safety Officer's Course, May 15-19, 1989

Introduction to Radon and Radon Measurement, Rutgers University, April 16, 1990

Packaging and Transportation of Radioactive Waste, US Ecology, August 20-22, 1991

Radiation Safety Training and Management, Stan A. Huber Consultants, Inc., August 14, 1992

Low-Level Radioactive Waste Minimization Workshop, USDOE, November 29-30, 1994

Radioactive Waste Packaging and Shipping Workshop, SEG, September 12, 1995

Transportation of Radioactive Materials, DGI Training Center, January 11, 2001

Radiation Safety Officer Training, Radiation Safety Academy, July 21-25, 2008

Experience:

Sanofi-aventis U.S. Inc, Bridgewater NJ. – January 2001 to present – Manager HSE

- Lead the development, implementation and management of HSE policies, programs and processes for ~1500 employees to achieve compliance with corporate and regulatory requirements.
- Direct HSE activities and ensures proper integration and coordination with functions represented at the site.
- Anticipate and respond to health, safety and environment issues. Aid in the importation of new technologies to the site and provide HSE risk assessment and support.
- Provide expert technical HSE support for all site organizations. Oversee industrial hygiene programs and function as site Chemical Hygiene Office, Biological Safety Officer and Assistant Radiation Safety Officer.
- Assist Radiation Safety Officer with implementation of various elements of the ionizing radiation safety program for the site, including radioactive package receipt, dosimetry program, sealed source inventory/leak tests, monthly wipe tests, survey equipment calibrations, training, laboratory inspections, protocol reviews.

### Experience Continued:

*Novartis Pharmaceuticals Corporation*, Summit NJ – January 1997 to January 2001 -  
Health Safety Officer/Radiation Safety Officer/Biosafety Officer

- Implemented and managed comprehensive laboratory safety, radiation and biological safety programs in an R&D environment supporting ~850 scientists including emergency response planning for spills, accidents and incidents. Directly communicate health, safety and industrial hygiene program issues, status and compliance matters to senior management in both the U.S. and Switzerland.
- Functioned as Assistant Radiation Safety Officer and Radiation Safety Officer, assuring compliance with all elements of state and federal government-issued multi-site broad-scope radioactive materials licenses. Managed by-product radioactive materials under an NRC Type A broad scope license, 2200 Ci Cs-137 irradiator under an NRC specific irradiator license, and radiation producing machines (medical X-ray, X-ray analyzers, electron microscopes) under the NJ State radiation producing machine programs.
- Served as technical transportation consultant. Coordinated and monitored hazardous materials shipping/receiving activities within R&D against compliance standards. Developed transportation guides to facilitate the shipping and receiving of hazardous materials. Obtained and maintained the appropriate licenses and permits for the import and export of research materials.

*Sandoz Pharmaceuticals Corporation*, East Hanover, NJ - September 1986 to December 1996 - Assistant Radiation Protection Officer /Assistant Biological Safety Officer

- Supported Radiation Protection Officer and Biological Safety Officer in managing the radiation and biological safety programs. Functioned as the deputy to the Radiation Protection Officer and the Assistant Director, Environmental Health and Safety. Administered by-product radioactive materials safety programs under an NRC specific and Type A broad scope license, 2200 Ci Cs-137 irradiator under an NRC irradiator license, and NORM (Indium-111) under a NJ State radioactive materials license.
- Conducted routine surveillance and audits of the R&D facilities for safety performance. Assured regulatory compliance with federal, state, and local laws by monitoring all areas in R&D against compliance standards.
- Recommended and promulgated safety policies and procedures, designed and conducted employee safety training programs, and maintained radiation safety records subject to regulatory audits.
- Performed as consultant to research personnel on the safe handling, storage, disposal and shipping of hazardous research materials.
- Responded to and documented emergency situations that involved contamination accidents, incidents and spills of biological, chemical and radioactive materials.
- Conducted site inspections and audits of waste disposal facilities for the treatment and disposal of radioactive and biological wastes.

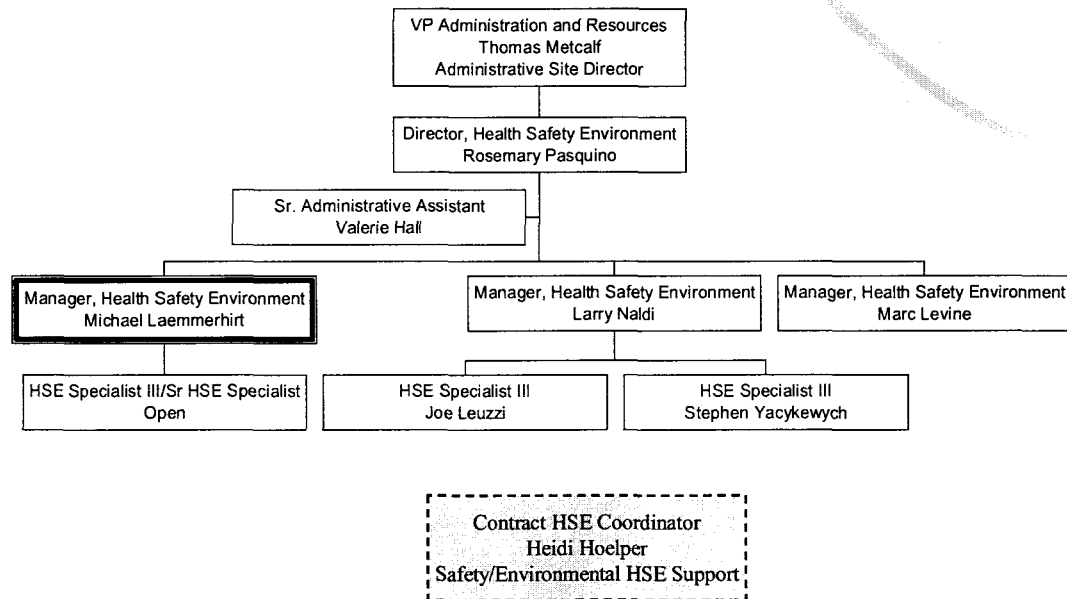
### RSO Duties/Responsibilities – No Change

RSO Organization Chart and Delegation of Authority – The current organizational chart can be found in Attachment 1. The delegation of Authority that will be communicated once the license amendment is approved can be found in Attachment 2.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS – No change
9. FACILITIES AND EQUIPMENT – No change
10. RADIATION SAFETY PROGRAM – No change
11. WASTE MANAGEMENT – No change



# Sanofi-aventis U.S. Inc. Bridgewater Site Direction Health Safety & Environment





I N T E R N A L   M E M O

Dear Colleagues,

Michael Laemmerhirt has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of byproduct (radionuclides) material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective action; verifying implementation of corrective actions; ensuring compliance with regulations for the use of byproduct 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.

Thomas Metcalf  
Vice President, Administration & Resources  
Deputy Director of US Sites – Research and Development  
Administrative Site Director – Bridgewater & Bethesda

This is to acknowledge the receipt of your letter/application dated

7/25/08, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment (29-15354-01)  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142664.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.